A Longitudinal Study to Investigate Changes in Functional Ability and Concerns in Head Neck Cancer Patients Undergoing Neck Dissection

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Abstract

Introduction:

The study investigated changes of shoulder/neck range of motion (ROM), shoulder strength, patient concerns and quality of life at pre-surgery and 1-month following neck dissection surgery.

Method:

Participants were 30 head and neck cancer patients selected for unilateral neck dissection. Shoulder/neck ROM and shoulder strength were measured at pre-surgery and 1-month post-surgery. The Patient Concerns Inventory-Level of Importance, University of Washington Quality of Life, Shoulder Pain and Disability Index and Neck Dissection Impairment Index were completed at the same time periods.

Result:

Significant drops in ROM and strength were found after surgery. Patients’ concerns changed over time. Significant correlations between the PCI-LOI and the UWQOL support cross-sectional convergent validity of the PCI-LOI.

Conclusion:

Decreased ROM and strength were observed on the affected side after surgery. Patients’ concerns changed over time. Identification of these concerns might help health professionals to focus on these specific patient needs.

Keywords

Head and neck cancer, range of motion (shoulder and neck), shoulder strength, neck dissection surgery, patients concern and quality of life.
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Chapter 1

1 Introduction

Head and neck cancer (HNC) does not only threaten physical wellness, but is a very devastating experience for an individual. The disease itself as well as the treatment modalities have effects on multiple areas of an individual’s life. The treatment might lead to deformities and has an adverse impact on psychological and social life (Murphy, Ridner, Wells, & Dietrich, 2007). The evaluation of the physical and psychosocial outcomes of HNC and its treatment are of great importance (Murphy et al., 2007; Hanks, Cherny, Christakis, & Kaasa, 2011). Moreover, the necessity to evaluate treatment-related morbidity and daily functional ability of the patient who undergoes the HNC treatment (Hammerlid, Silander, Hörnestam, & Sullivan, 2001) is essential.

Patients with HNC experience unique problems such as functional impairment/disruption in daily activities and disfigurement associated with malignancy and subsequent treatments (Hammerlid et al., 2001; Goldstein, Hynds Karnell, Christensen, & Funk, 2007; Murphy et al., 2007; El-Deiry, Futran, McDowell, Weymuller, & Yueh, 2009). Surgical resection alone or in conjunction with radiotherapy and/or chemotherapy remain as the main treatment for HNC (Brizel et al., 1998; Pignon, Bourhis, Domenge, & Designé, 2000; Forastiere et al., 2003; Shah & Gil, 2009). Neck dissection surgery is often associated with post-surgical morbidities (van Wilgen, Dijkstra, van der Laan, Plukker, & Roodenburg, 2004a) impacting swallowing, speech, oral symptoms (e.g. taste change, xerostomia¹, dental decay, mucosal sensitivity), appearance, sense of smell, pain, and shoulder and neck dysfunction (Myers et al., 1999; Murphy et al., 2007; McNeely et al., 2001).

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¹ Xerostomia - dryness of mouth.
Hence, patients can go through mental stress, physical and emotional suffering and reduced socialization (Kanatas, Ghazali, Lowe, & Rogers, 2012) affecting overall well-being (Karnell, Funk, & Hoffman, 2000; Martino & Ringash, 2008; Chaukar et al., 2009).

Shoulder and neck disability associated with treatment for neck dissection is well recognized. Shoulder impairment (reduction in range of motion, strength), pain (Goldstein et al., 2014b) and reduced neck mobility, and neck stiffness (van Wilgen, Dijkstra, van der Laan, Plukker, & Roodenburg, 2004) have been frequently reported after neck dissection surgery. HNC patients with neck dissection surgery experience shoulder dysfunction, chronic neck and shoulder pain, cosmetic deformity, and cutaneous paresthesia as possible adverse effects of treatment that affect the long term quality of life (QOL) of patients (Rogers et al., 2004; Bradley et al., 2011).

Quality of life after treatment and outcome measurement in cancer treatment (Sayed et al., 2009) have both become increasingly important issues from research and clinical points of view. Quality of life is a global multidimensional construct to assess the patient’s sense of well-being related to the disease or treatment (Osoba, 1994). Specifically, health-related quality of life (HRQOL) is a subjective evaluation assessing physical, psychological and social domains of health from a patient’s perspective about their values, beliefs, experience and expectation in life (Patrick, Bush, & Chen, 1973; Brook et al., 1983; Testa & Simonson, 1996). The World Health Organization (WHO) defines QOL as “an individual’s perception of their position in life, in the context of their culture and values system where they live, and in relation to their goals, expectations, standards, and concerns. It is a broad ranging concept, incorporating in a complex way a

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2 Paresthesia is a sensation of tingling, tickling, pricking, or burning of a person's skin with no apparent physical cause
person’s physical health, psychological state, level of independence, social relationships, personal beliefs and relationship to salient features of the environment” (World Health Organization, 1998).

The Patient Concerns Inventory (PCI) is a holistic, patient-reported screening tool to detect unfulfilled needs and undetected concerns of HNC patients (Ghazali, Kanatas, et al., 2012; Ghazali, Roe, Lowe, & Rogers, 2013). It helps health care providers to identify patients concerns which have remained undisclosed or unnoticed (Rogers, El-Sheikha, & Lowe, 2009). For this research, we incorporated (with the developer’s permission) a Likert scale to the PCI for each item in all domains, in which the patient can report the importance of their concerns. This modified tool was named the Patient Concerns Inventory-Level of Importance (PCI-LOI).

As a need to detect specific concerns for the HNC population, the thesis was structured to identify physical changes in strength and range of motion for the shoulder and neck, to evaluate concurrent changes in patients’ concerns related to these physical changes and overall QOL after neck dissection surgery. Moreover, the aim is also to assess whether the PCI-LOI is valid specifically for HNC patients like other validated questionnaires intended for shoulder and neck morbidity and QOL.
Chapter 2

2 Review of Literature

To aid in understanding HNC and the impact it leaves on patients, this chapter provides an overview of the disease, its treatment modalities, and shoulder and neck morbidity relating to the disease. The QOL of HNC patients after surgery is also discussed.

2.1 Head and Neck cancer

Head and neck cancers are epithelial malignancies arising from the mucosa in the upper aero-digestive tract including the oral cavity/lip, nasopharynx, oropharynx, hypopharynx, larynx, the para-nasal sinuses and the salivary glands. About 90% of HNC are squamous cell carcinomas which have different histopathological variants involving different anatomical sites (Curado & Hashibe, 2009; Mehanna, Paleri, West, & Nutting, 2010).

The combination of cigarette smoking and alcohol consumption is the major risk factor, accounting for almost 75% of HNC cases (Argiris, Karamouzis, Raben, & Ferris, 2008; Conway et al., 2009). Cigar and pipe smoke also separately play a role (Sturgis, 2014). The human papilloma virus (mainly HPV 16 and to a lesser extent HPV 18), the Epstein Barr virus (EBV), and genetic pleomorphism\(^3\) also cause HNC and an increased incidence has been observed in patients with a family history of HNC in first degree relatives. Other risk factors include environmental/occupational exposure to certain chemicals, poor dental hygiene, low dietary consumption, and chewing of a betel nut

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\(^3\) the occurrence of various distinct forms by a single organism or within a species
wrapped in a betel leaf (Argiris et al., 2008; Marur & Forastiere, 2008; Mehanna et al., 2010).

Treatment options are complicated and involve a multidisciplinary team. About two-thirds of patients present with advanced stages involving lymph nodes; 10% metastatic cases have also been reported. Surgery along with chemotherapy and/or radiotherapy have long been the main treatment modalities depending on the site, extent, staging, grading and dissectibility of the tumor as well as patient factors (Argiris et al., 2008; Pignon et al., 2009).

In Canada, cancer is the leading cause of death (Canadian Cancer Statistics, 2015). Head and neck cancer is among the 10 most common malignancies in men in the world (Curado & Hashibe, 2009). The incidence of HNC is three-fold higher in men than women (Marur & Forastiere, 2008). Mouth and oropharynx malignancy is the 10th most common cancer worldwide and the seventh most common cause of death (World Health Organization, 2008). The incidence is higher in more developed countries. In 2008, it was estimated there would be 550,319 new head and neck cancer cases in the world in which an estimated 408,735 cases would be in males and 141,584 in females; the expected number of deaths was 229,903 in males and 75,193 in females (Curado & Boyle, 2013). The most common sites found were the oral cavity followed by the larynx and pharynx (World Health Organization, 2008; Mehanna et al., 2010; Ferlay et al., 2010; Curado & Boyle, 2013).

In 2015, there was an estimated 4400 new cases of oral cancer in Canada; approximately 2900 in males and 1450 in females. There were 1050 new cases for the larynx and 6300 for thyroid cancer. Excluding thyroid cancer, all the other forms show male predominance. In 2015, estimated deaths included 1200 due to oral cancer and 380 due to laryngeal cancer (Canadian Cancer Statistics, 2015). The incidence of HNC increases
with advanced age although a rapid rise of incidence in young adults has also been reported (Curado & Boyle, 2013). Head and neck cancer has become a major health burden worldwide, due to its nature and course, its treatment and its treatment-related morbidity.

The nature of HNC leaves several negative impacts on physical and mental functioning of patients. Disability as treatment-related morbidity is a very critical and complex issue in the HNC population (Hammerlid et al., 2001). The International Classification of Functioning, Disability & Health (ICF) of the WHO has rephrased ‘disability’ as impairments, limited activities and restricted social involvement (World Health Organization, 2001; World Health Organization, 2004). Impairments are referred to as significant loss or alteration in physiological functions of normal anatomy (World Health Organization, 2001; Goldstein et al., 2014b). The ICF is a universally accepted model that specifically focuses on the aftermath of the disease, its treatment and describes the outcome measures (World Health Organization, 2001). Hence, the ICF combined with specifically designed tools for the HNC population might ease clinical decision-making and ensure holistic assessment. Holistic assessment in cancer patients is the assessment of patients’ subjective needs in different areas of health which helps healthcare providers to have a depth of understanding about patient concerns and provide supportive care accordingly (Ghazali, Roe, Lowe, & Rogers, 2015).

2.2 Management and different cervical levels

Distant metastasis is frequently into the lymph nodes in HNC. In 1950, multi-modality therapy was first introduced combining surgery and radiation therapy in locally advanced HNC (Murphy, Gilbert, & Ridner, 2007). Surgical resection with or without radiotherapy and/or chemotherapy is the treatment of choice to remove the metastatic tumor from its primary and metastatic site (Marcy & Bilir, 2004). The treatment modality depends on the location of the primary tumor, its size and stage according to TNM (tumor, nodes,
metastasis) classification, grade, lymph node involvement, site of distant metastasis and patients’ physical condition. Commonly HNC has a tendency to metastasize in the cervical lymph nodes and the pattern of metastasis is to some extent predictable (Fukano, Matsuura, Hasegawa, & Nakamura, 1997; Korkmaz et al., 2002; Chummun, McLean, & Ragbir, 2004).

Samant & Robbins stated that “neck dissection refers to a surgical procedure in which the fibrofatty soft tissue content of the neck is excised to remove the lymph nodes contained therein”. The goal of the surgery is to remove the affected tissues in the lymph nodes (Samant & Robbins, 2003). The type of surgery depends on the level of lymph node involved. The most popular nomenclature of different lymph nodes is described by the Memorial Sloan-Kettering Cancer Centre which describes the metastasis patterns in HNC (Samant & Robbins, 2003). According to this, lymph nodes in the cervical area are grouped into levels I to V. Level I is submandibular and submental; upper, middle and lower jugular are levels II, III, and IV; and the posterior triangle nodes are level V (Shah, 1990; Samant & Robbins, 2003; Chummun et al., 2004).

The American Academy of Otolaryngology- Head and neck Surgery (AAO-HNS) and The American Society for Head and Neck Surgery (ASHNS) has classified the lymph node groups into 6 levels and 6 sublevels. They are submental (sublevel IA), submandibular (sublevel IB), upper jugular (includes sublevel IIA,IIB), middle jugular (level III), lower jugular (level IV), posterior triangle group (includes sublevels VA and VB) and anterior compartment group (level VI) (Robbins et al., 2002). Table 2.1 provides a description of the anatomical boundaries of the sublevels.
<table>
<thead>
<tr>
<th>Level</th>
<th>Superior</th>
<th>Inferior</th>
<th>Anterior (medial)</th>
<th>Posterior (lateral)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IA</td>
<td>Symphysis of mandible</td>
<td>Body of hyoid</td>
<td>Anterior belly of contralateral digastric muscle</td>
<td>Anterior belly of ipsilateral digastric muscle</td>
</tr>
<tr>
<td>IB</td>
<td>Body of mandible</td>
<td>Posterior belly of muscle</td>
<td>Anterior belly of digastric muscle</td>
<td>Stylohyoid muscle</td>
</tr>
<tr>
<td>IIA</td>
<td>Skull base</td>
<td>Horizontal plane defined by the inferior body of the hyoid bone</td>
<td>Stylohyoid muscle</td>
<td>Vertical plane defined by the spinal accessory nerve (SAN)</td>
</tr>
<tr>
<td>IIB</td>
<td>Skull base</td>
<td>Horizontal plane defined by the inferior body of the hyoid bone</td>
<td>Vertical plane defined by the SAN</td>
<td>Lateral border of sternocleidomastoid (SCM) muscle</td>
</tr>
<tr>
<td>Vertical Level</td>
<td>Description of Plane</td>
<td>Landmarks</td>
<td>Landmarks</td>
<td>Landmarks</td>
</tr>
<tr>
<td>---------------</td>
<td>----------------------</td>
<td>-----------</td>
<td>-----------</td>
<td>-----------</td>
</tr>
<tr>
<td>III</td>
<td>Horizontal plane defined by the inferior body of hyoid bone</td>
<td>Horizontal plane defined by the inferior border of the cricoid cartilage</td>
<td>Lateral border of the sternohyoid muscle</td>
<td>Lateral border of the SCM or sensory branches of cervical plexus</td>
</tr>
<tr>
<td>IV</td>
<td>Horizontal plane defined by the inferior border of the cricoid cartilage</td>
<td>Clavicle</td>
<td>Lateral border of the sternohyoid muscle</td>
<td>Lateral border of the SCM or sensory branches of cervical plexus</td>
</tr>
<tr>
<td>VA</td>
<td>Apex of the convergence of the SCM and trapezius muscle</td>
<td>Horizontal plane defined by lower border of cricoid cartilage</td>
<td>Posterior border of the SCM or sensory branches of cervical plexus</td>
<td>Anterior border of the trapezius muscle</td>
</tr>
<tr>
<td>VB</td>
<td>Horizontal plane defined by the lower border of cricoid cartilage</td>
<td>Clavicle</td>
<td>Posterior border of the SCM or sensory branches of cervical plexus</td>
<td>Anterior border of the trapezius muscle</td>
</tr>
<tr>
<td>VI</td>
<td>Hyoid bone</td>
<td>Suprasternal</td>
<td>Common carotid artery</td>
<td>Common carotid artery</td>
</tr>
</tbody>
</table>

Adapted from (Robbins et al., 2002)
2.3 Types of Neck Dissection

In squamous cell carcinoma of HNC, the accepted single most important adverse prognostic factor is cervical lymph node metastasis. Neck dissection with its various forms is the standard treatment option for HNC (Ferlito et al., 2011; Ferlito, Robbins, Silver, Hasegawa, & Rinaldo, 2009; Samant & Robbins, 2003). Radical neck dissection is a procedure that was introduced by Crile (Crile, 1905; Crile, 1906; Ferlito et al., 2009). Later it was refined by Martin and colleagues and remains as a fundamental tool in the treatment of patients of HNC (Martin, Del Valle, Ehrlich, & Cahan, 1951; Ferlito et al., 2011). The neck dissection classification system was revised in 2002 and 2008 by the American Head and Neck Society and the American Academy of Otolaryngology–Head and Neck Surgery (Robbins et al., 2002; Robbins et al., 2008; Ferlito et al., 2009). A brief description of each type follows.

**Radical neck dissection:**

Radical neck dissection (RND) was originally described by George Crile in 1906. It involves the total excision of the tumor, ipsilateral cervical lymph nodes from I to V, extending from the inferior border of the mandible to the clavicle, from the lateral border of the sternohyoid muscle, hyoid bone and contralateral anterior belly of the digastric muscle medially, to the anterior border of the trapezius muscle. The sternocleidomastoid (SCM) muscle, the spinal accessory nerve (SAN) and the removal of the internal jugular vein (IJV) from the ipsilateral side are included (Ferlito & Rinaldo, 2008; Robbins et al., 2002). The posterior auricular, suboccipital, perifacial, buccinators, and retropharyngeal nodes or the central compartment nodes are not removed (Ferlito et al., 2011; Robbins et al., 2008). This procedure is applicable to patients with advanced stage of the disease, with extracapsular involvement to SAN, IJV and SCM muscle (Samant & Robbins, 2003). Radical neck dissection is the standard basic procedure for cervical
lymphadenectomy and all other procedures are the result of the modification of this standard procedure (Chummun et al., 2004).

**Modified radical neck dissection:**

This procedure is carried out in clinically palpable metastatic cases (Samant & Robbins, 2003). It involves removal of all lymph nodes from I to V with preservation of at least one of the non-lymphatic structures (SAN, IJV, SCM) (Ferlito et al., 2009; Ferlito et al., 2011). The structure that is preserved must be named specifically; e.g. modified radical neck dissection with the preservation of IJV (Robbins et al., 2002). Gross metastasis in the nerve, vein, and muscle may lead to conversion to radical neck dissection, though the involvement of all these three non-lymphatic structures is only found in very advanced stages (Samant & Robbins, 2003).

**Selective neck dissection:**

Preservation of one or more lymph nodes dissected in RND is termed selective neck dissection. The lymph node groups removed are dependent on the metastatic pattern (Robbins et al., 2002). This is performed usually in patients having greater than 15-20% chances of microscopic nodal metastasis, which might not be clinically or radiologically evident (Weiss, Harrison, & Isaacs, 1994). Table 2.2 provides a description of different types of selective neck dissection (Robbins et al., 2002)
**Table 2.2: Types of selective neck dissection**

<table>
<thead>
<tr>
<th>Type of Selective Neck Dissection (SND)</th>
<th>Sublevels</th>
</tr>
</thead>
<tbody>
<tr>
<td>SND for oral cavity cancer</td>
<td>SND (I-III/IV)</td>
</tr>
<tr>
<td>SND for oropharyngeal, hypopharyngeal and laryngeal cancer</td>
<td>SND (II-IV)</td>
</tr>
<tr>
<td>SND for cutaneous malignancies</td>
<td>SND (II-V, post auricular, suboccipital)</td>
</tr>
<tr>
<td>SND for midline structures of the anterior lower neck</td>
<td>SND (VI)</td>
</tr>
</tbody>
</table>

(Robbins et al., 2002)

**Extended neck dissection:**

Excision of additional lymph nodes, with or without non-lymphatic structures (blood vessels, muscle, nerves) which are not routinely included in RND is termed extended neck dissection. This surgery is indicated in more advanced stages of the disease. The lymph nodes removed are retropharyngeal, superior mediastinal, buccinators/perifacial, periparotid, postauricular, and suboccipital. The external carotid artery, hypoglossal nerve, vagus nerve and portions of the prevertebral and paraspinal muscles are also removed if involved with the tumor (Robbins et al., 2002; Ferlito et al., 2011).
Table 2.3 Definitions of different types of neck dissection

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Definitions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radical</td>
<td>Removal of lymph node levels I–V, SCM, SAN, and IJV.</td>
</tr>
<tr>
<td>Modified</td>
<td>Removal of lymph node levels I–V (as in radical neck dissection), but preservation of at least one of the non-lymphatic structures (SCM, SAN, and IJV). Each non-lymphatic structure removed should be named.</td>
</tr>
<tr>
<td>Selective</td>
<td>Preservation of one or more lymph node levels relative to a radical neck dissection.</td>
</tr>
<tr>
<td>Extended</td>
<td>Removal of an additional lymph node level or group or a non-lymphatic structure relative to a radical neck dissection (muscle, blood vessel, nerve). An example of other lymph node groups can be superior mediastinal, parapharyngeal, retropharyngeal, peri-parotid, postauricular, suboccipital, or buccinator. An example of other non-lymphatic structure can be external carotid artery, hypoglossal or vagus nerves.</td>
</tr>
</tbody>
</table>

SCM- Sternocleidomastoid, SAN- Spinal accessory nerve, IJV- Internal jugular vein

Cited in (Ferlito et al., 2009)

**Radiotherapy:**

Radiotherapy is a localized treatment that uses radiation to treat tumors (Burnet, Thomas, Burton, & Jefferies, 2004; UK, 2016). Radiotherapy is used when treating HNC
patients undergoing neck dissection, alone or in combination with chemotherapy, depending on the stage of the cancer and patient’s condition. High-energy waves or particles destroy the cancer cells. Radiotherapy damages the DNA (deoxyribonucleic acid) of the cancer cell so that it stops growing (Canadian Cancer Society, 2016b). It has been shown to reduce the neck morbidity rate by 50% used either pre or post-neck dissection (Chummun et al., 2004). Post-operative radiotherapy as an adjunct reduces the complication rate of the surgery (Chummun et al., 2004). Radiotherapy is useful in cases of large primary tumors with a positive margin in multiple nodal metastasis (Byers, 1985; Chummun et al., 2004). Altered fractionated radiotherapy (a prototype of altered radiotherapy) (Antognoni, Corvò, Zerini, & Orecchia, 2005) and Cetuximab (a type of monoclonal antibody) combined with radiotherapy has also been shown to improve the overall survival rate (Bourhis et al., 2006; Bonner et al., 2010).

Chemotherapy:

Previous research showed chemotherapy in combination with radiotherapy has better prognosis than radiotherapy alone. Chemotherapy uses drugs to kill the malignant cells. Several chemotherapy drugs are administered together to get the effect (Canadian Cancer Society, 2016a). The combination treatment of radiotherapy and chemotherapy in locally advanced HNC was found to be more effective and less toxic (Brizel et al., 1998; Bernier & Cooper, 2005) and has fewer late complications compared to radiotherapy alone (Bernier et al., 2004). Cooper and colleagues (2004) also showed an increased disease-free survival rate by adding chemotherapy to the postoperative radiotherapy schedule. It offers better quality of life (QOL) due to the absence of or less pain, less depression and a better mental condition (List & Bilir, 2004).

\[4\] Cancer cells come right out to the edge of the removed tissue.
Reconstructive surgeries:

Neck dissection in HNC patients often leads to complex functional and cosmetic issues that requires reconstructive surgery to restore function. The extent of the resection determines the type of reconstructive procedure. The goal of reconstructive surgeries in HNC is mainly to restore tissue volume and heal ablative tissue surfaces and tissue linings (Chiu, Liu, & Friedlander, 2009). Several types of free flaps are routinely used in HNC surgery such as radial forearm, fibula, scapula, and anterolateral thigh flap (Mitchell, 2012). The pectoralis major pedicled flap has been used widely since Ariyan described this reconstructive procedure in 1979 (Ariyan, 1979). Each reconstructive surgery has its own advantages and disadvantages. Research has shown reconstructive surgeries in combination with neck dissection might lead to complications due to several factors and might lead to post-surgical issues related to low QOL (Clark et al., 2007).

2.4 Shoulder function

The shoulder girdle is composed of the sternoclavicular joint, the acromioclavicular joint, the glenohumeral joint and the scapulothoracic articulation. Muscle force at these joints produces a coordinated movement pattern known as scapulohumeral rhythm (Abelew, Tovin, & Greenfield, 2001). The movement seems localized to the glenohumeral joint, but generally the whole shoulder girdle is involved allowing a wide range of motion for the arm and hand (Hall, 1999; Williams Jr, Shakil, Klimkiewicz, & Iannotti, 1999; Kreitner & Löw, 2000). The shoulder joint is the most flexible joint in the human body having a wide range of motion (flexion, extension, adduction, abduction, external rotation, internal rotation and circumduction). These movements require coordination of muscles which are attached to the scapula, humerus and clavicle (Quillen, Wuchner, & Hatch, 2004). The functional muscles are the rotator cuff muscles (teres minor,
The muscles of the shoulder girdle give support for shoulder movements (Selcuk, Selcuk, Bahar, & Dere, 2008). The trapezius plays a major role in shoulder function such as abduction, adduction and rotation (Selcuk et al., 2008). The trapezius is made up of three parts (Brown, Burns, & Kaiser, 1988; Nori, Soo, Green, Strong, & Miodownik, 1997). The upper and lower thirds rotate the scapula at the time of abduction and the middle third stabilizes the scapula (Hollinshead, 1982; Weisberger, 1987). The motor innervation of the upper part of the trapezius muscle is the SAN and the rest is supplied by the posterior parts of the 3rd and 4th cervical nerve roots (Brown et al., 1988; Karuman & Soo, 1996).

Resection or manipulation of the SAN during neck dissection surgery usually leads to shoulder morbidity. The SAN provides predominant motor innervation to the trapezius and SCM muscles (Heico-Rüdiger, 1992; Kierner, Zelenka, & Burian, 2001; El Ghani et al., 2002) and is at highest risk of being deliberately resected in its course during the procedure through level 2. The nerve is at risk of being sacrificed if it is invaded by the tumor or if it is closer to the metastatic lymph node during the procedure after radiotherapy. Dysfunction may also occur even if it is preserved or macroscopically intact, due to dissection and devascularization (El Ghani et al., 2002; van Wilgen et al., 2004a).

Shoulder morbidity is usually observed in the early postoperative period following most RND and in some SAN-sparing neck dissection (Stuiver et al., 2008), although SND patients tend to have much less shoulder impairment and less limited activity (Dijkstra et al., 2001; Selcuk et al., 2008). Ewing and Martin first described the “shoulder syndrome” in patients after radical neck dissection (Ewing & Martin, 1952). They reported significant shoulder impairments including chronic and non-specific shoulder pain,
limited abduction and reduction in active ROM and anatomical deformity (Ewing & Martin, 1952). The anatomical shoulder impairment or “shoulder syndrome” includes shoulder droop, winged scapula, protraction, inability to shrug, dull non-localizing pain exacerbated particularly by shoulder abduction and a limitation in shoulder abduction (Taylor et al., 2002; Carenfelt & Eliasson, 2009). In 1961, Nahum and colleagues also reported the same result (Nahum, Mullaly, & Marmor, 1961). This shoulder syndrome is largely affected by the extent of neck dissection surgery and significantly affects an individual’s QOL by restricting daily activities, personal work, social life, professional life, and recreational activities (Schuller et al., 1983; Short et al., 1984; Heald, Riddle, & Lamb, 1997; Terrell et al., 2000; Shah, Har-El, & Rosenfeld, 2001; Taylor et al., 2002; El Ghani et al., 2002; Rogers et al., 2004; Remmler et al., 2006; Stuiver et al., 2008). Frozen shoulder and brachial plexus lesions have also been reported after neck dissection (Patten & Hillel, 1993; Dijkstra et al., 2001). Pain, adhesive capsulitis, skin tightness, and the effect of radiotherapy also lead to reduced shoulder and neck mobility (Merve, Mitra, Swindell, & Homer, 2009).

Shoulder impairment in strength and ROM, pain, physical disfigurement, and limited activity have been reported frequently following RND (Fialka & Vinzenz, 1988; van Wilgen et al., 2004). Previous research has shown that RND patients have significantly poorer outcome in terms of shoulder ROM, strength, pain, and activity limitation compared to MRND in the long term period (>6 months post-surgery) (Taylor et al., 2002; Güldiken et al., 2005; Goldstein et al., 2014). Along with shoulder complaints, neck morbidity can be affected directly by neck dissection resulting in pain, reduced ROM, loss of sensation in the neck and shoulder area (Nahum et al., 1961; Chaplin & Morton, 1999; Dijkstra et al., 2001; Piazza, Cappiello, & Nicolai, 2002; Speksnijder et al., 2013). Following RND, shoulder dysfunction is found to be the most important cause of long-term morbidity (Saunders, Hirata, & Jaques, 1985). Severe upper extremity motor impairment along with neck stiffness, and shoulder pain radiating to the face have also
been reported in patients treated with RND (Leipzig et al., 1983). Heico-Rudiger reported that almost 72% of patients suffered shoulder problems after RND (Heico-Rüdiger, 1992).

A RND was later modified that preserves the SAN (modified radical neck dissection and selective neck dissection) and limits the extent of shoulder dysfunction resulting from RND (Bocca, Pignataro, & Sasaki, 1980; Bocca, Pignataro, Oldini, & Cappa, 1984; Medina & Byers, 1989). However, shoulder complaints following MRND and SND were still reported. Up to 40% shoulder impairment has been reported in patients with MRND (Salerno et al., 2002). Less shoulder syndrome was reported in SND compared to MRND (Witt & Rejto, 2007). Patients having level II to V SND have increased shoulder morbidity and may have impaired nerve conduction (Cappiello et al., 2005). Long term pain with activities like moving the arm, reaching above the shoulder or carrying heavy objects have also been reported (van Wilgen et al, 2003).

Another important contributor to shoulder dysfunction is radiation treatment (Chepeha et al., 2002; Bradley et al., 2011). Radiation therapy has a detrimental effect on subjective shoulder function regardless of neck dissection (Laverick et al., 2004). A 20% reduction in active shoulder ROM due to radiotherapy has been reported (Nowak, Parzuchowski, & Jacobs, 1989). Nowak and co-workers also reported that RND with reconstructive pectoralis major pedicled flap surgery and postoperative radiation therapy have led to reduced neck ROM (Nowak et al., 1989; van Wilgen et al., 2004b). Watkins and colleagues reported radiotherapy or chemo-radiation therapy along with SND do not have any detrimental effect on shoulder function (Watkins et al., 2011). However, reconstructive surgery such as a pectoralis major flap along with RND limits shoulder and neck function; (Haribhakti, Kavarana, & Tibrewala, 1993; Chaplin & Morton, 1999; Moukarbel et al., 2010).
According to previous research, SND leads to less shoulder morbidity. We wanted to determine whether SND alone or in combination with reconstructive surgery has any significant effect on ROM and strength in our patient population. Moreover, the local ENT surgeons wanted to know whether the previous literature was similar to the local patient population who had surgery for shoulder and neck mobility and shoulder strength.

2.5 Quality of life in HNC

Quality of life is a subjective, individual evaluation by the person and essentially (Doyle & Keith, 2005; Heutte, Plisson, Lange, Prevost, & Babin, 2014) is “a state of well-being which is a composite of two components; 1) the ability to perform everyday activities which reflect physical, psychological and social well-being; and 2) patient satisfaction with levels of functioning and the control of disease and/or treatment-related symptoms” (Gotay & Moore, 1992). Assessing health-related quality of life (HRQOL) is not simple in the HNC population because the tumor and the surgery involve diverse anatomical structures. It is of great importance to assess HRQOL outcomes in clinical practice as QOL measurement can provide information to guide clinical decision making and provide the best patient care (Rogers, Fisher, & Woolgar, 1999; Weymuller et al., 2000; Higginson & Carr, 2001; Rogers, 2009). The QOL studies inform the clinician about the impact of the treatment and its outcome. These studies facilitate communication between the clinician and the patients and help to identify the specific problem that is causing a significant impact on overall QOL. Research on QOL also guides the physician to screen for the problem and help prioritize problems occurring from treatment. This research minimizes the communication gap between the physician and patients and it helps in decision-making regarding treatment (Murphy et al., 2007). It is essential for health care personnel to identify patients’ priorities and concerns and to understand them (Kanatas et al., 2012). Patient concerns are an important issue and have become an integral part of the
clinical decision-making system that helps identify the specific need of patients. This has improved the significance of QOL research.

To date, the most important concerns in patients treated primarily by HNC surgery are speech, voice loss/disturbance, disfigurement/appearance, difficulty eating (swallowing, chewing), decreased activity, and pain (Rogers et al., 2002; Rogers, Laher, Overend, & Lowe, 2002; List & Bilir, 2004). Oral functions like swallowing, speech, chewing and eating are largely influenced, either by the location of the tumor or the different methods used to treat the tumor. Both speech and swallowing dysfunction have been found to significantly impact health-related QOL including self-esteem, emotion and socialization (Rinkel et al., 2009; Chen et al., 2001). Reports have shown that 75% of HNC patients complain of swallowing problems after treatment (Dwivedi et al., 2012). Hence, these are important issues affecting QOL in HNC survivors (Ghazali, 2012).

Patients undergoing neck dissection experience constriction of the neck muscle due to stiffness and are troubled due to appearance (Inoue et al., 2006). Depression, anxiety, social phobia and social avoidance have been reported as clinically significant, thereby reducing quality of life (Kohda et al., 2005). Another psychological issue is the fear of cancer itself, or its recurrence. In patients with HNC, shoulder/neck function seems to be less important initially as the primary concern remains survival (Sharp et al., 1999; List et al., 2000; Devins et al., 2013). An important sequela for post-treatment depression and anxiety is a highly significant rate of substance abuse and development of psychopathology. The surgery also might lead to cosmetic defects that may accelerate the inability to communicate and inability to swallow, eventually leading to social avoidance (Murphy et al., 2007).

In recent years, shoulder syndrome associated with neck dissection is recognized as an important post-surgical factor that affects quality of life (Shah et al., 2001) and the more
extensive the surgery is, the more surgical morbidities are observed post-surgically (Kuntz & Weymuller, 1999). Larger tumors leading to more extensive surgical resection usually results in greater morbidity.

Studies have attempted to assess the relationship between neck dissection in the HNC population and scores obtained from HRQOL questionnaires. The University of Washington Quality of Life (UWQOL) questionnaire is an HNC-specific questionnaire. Using the UWQOL, Laverick and colleagues found that patients who had neck dissection surgery had lower scores and worse QOL compared to patients who did not have neck dissection surgery, even after more than one year after surgery, (Laverick et al., 2004). The Neck Dissection Impairment Index (NDII) score was also lower in patients with MRND compared to SND (Taylor et al., 2002). The Shoulder Pain and Disability Index (SPADI) score was significantly higher meaning worse shoulder outcomes in patients having neck dissection with a reconstructive flap (Moukarbel et al., 2010).

The Patient Concerns Inventory (PCI) is a self-reported screening tool that is promoted as a means of detecting the patient’s concerns that may otherwise go unnoticed by clinicians. It is an important mode of communication in the clinical setting that identifies patients’ unseen needs (Ghazali & Rogers, 2012). It helps to identify the concerns that patients want to discuss with their health care provider (Rogers, Scott, Lowe, Ozakinci, & Humphris, 2010). The PCI encompasses items from general and HNC-specific questionnaires and topics identified from discussions with patients and professionals involved in HNC care (Ghazali, Lowe, & Rogers, 2012). It helps the consultant to provide necessary support on an individual basis (Rogers, Sheikha, & Lowe, 2009). To date it accurately identifies patients with swallowing, speech dysfunction and psychological stress in combination with the UWQOL (Ghazali, 2012; Kanatas et al., 2012). Our goal was to assess the magnitude of changes in functional ability in shoulder/neck function and the scores obtained from the PCI-LOI. We wanted to assess whether the score in
PCI-LOI is related to HRQOL. The complicated nature of HNC itself along with its treatment reduces quality of life. Hence, it is important to find out the subjective issues that concern patients.

2.6 Study hypotheses:

1. Shoulder/neck ROM and shoulder strength would diminish post-surgery irrespective of the type of neck dissection.

2. Patients’ concerns would change depending on patients’ physical and psychological condition before and after surgery.

3. Total PCI-LOI scores would significantly correlate with patients’ scores on UWQOL, SPADI and NDII.

2.7 Objectives:

The tumor itself or the treatment might lead to more complications in HNC patients. Hence detecting their specific needs both subjectively and clinically is important. From this perspective, the objectives of the thesis were to:

1. Detect physical changes in strength and range of motion for the shoulder and neck on the operative side.

2. Evaluate changes in patients’ concerns and overall QOL after neck dissection surgery.

3. Assess cross-sectional convergent construct validity of the PCI-LOI questionnaire by significant inverse correlation with UWQOL score (a validated patient reported outcome
measure that assesses QOL in head neck cancer patient who had neck dissection). We also aimed to assess the correlation of total PCI-LOI scores with SPADI and NDII which are validated outcome measures to detect the shoulder and neck disability respectively in the same patient populations.
Chapter 3

3  Introduction

This chapter describes the study design, procedure of the measurements for the ROM and strength tests, outcome measures, sample size and statistical analysis.

3.1  Methods

Study design:

This prospective longitudinal cohort study was conducted between June 2014 and February 2015, at the Victoria Hospital-London Health Sciences Centre (LHSC).

Participants:

All of the participants were diagnosed with HNC and were selected for neck dissection surgery. To obtain a homogenous group of patients, the following eligibility criteria were applied.

Inclusion Criteria:

a) Patients have been diagnosed with head and neck cancer at Victoria Hospital;

b) Over 18 years of age;

c) Scheduled for neck dissection (unilateral) alone or in conjunction with various reconstruction flap procedures.
Exclusion criteria:

a) Patients with language or comprehension barrier;

b) Central neck dissection or limited neck dissection;

c) Patients with thyroid cancer;

d) Patients too ill to be interviewed;

e) Patients having bilateral neck dissection.

The study was approved by Western University’s Health Sciences Review Ethics Board (HSREB – see Appendix A) and by the Lawson Clinical Research Impact Committee (CRIC-see Appendix B) of the LHSC.

Procedure:

The participants were diagnosed cases of HNC, admitted to Victoria Hospital, LHSC, between June 2014 and February 2015. The otolaryngologists in the Ear, Nose, and Throat clinic screened and diagnosed the patient population. Prior to surgery, at the pre-admit clinic, each of the patients had been fully informed of the purpose of the study. Written consent was obtained before participation in the study.

A physical assessment was performed, including active range of motion (ROM) and strength for shoulder and neck function. Measurements of ROM were obtained using a Dualer IQ inclinometer (JTECH Medical, Midvale, United States); muscle strength was measured with a hand-held dynamometer - Microfet 2 (Hoggan Health Industries Salt Lake City, United States).
Range of motion:

Inclinometer: The Dualer IQ inclinometer is reliable and valid (Kolber & Hanney, 2012) and ensures accurate measures for shoulder ROM. It is clinically accepted, easy to use and does not cause any discomfort (Dover & Powers, 2003). An inclinometer is considered best for its clinimetric properties and practical utility (de Koning et al., 2008).

Neck ROM:

The patient was supine on the bed with the head in a neutral position. An inclinometer was placed on the vertex\(^5\) with a strap. The right and left lateral rotation ROM was assessed in the coronal plane. The starting point was “0” shown on the inclinometer, and the patient was instructed to rotate the neck from the neutral position, without any discomfort, and without lifting their back or neck from the bed. Once the measurement was recorded, the patient returned their neck to the neutral position. The measurement was repeated three times on both sides.

Shoulder ROM:

We assumed that shoulder flexion and external rotation were likely to change after the surgery and decided to test these two ROM to measure the change following surgery. We also intended to measure the shoulder abduction. However, this ROM test caused pain in the shoulder during the measurement. In some cases, patients complained of persistent pain which lasted for a few days. Hence, we decided not to continue measuring shoulder abduction.

\(^5\) Vertex- The highest point of the skull.
Flexion: The patient was in the standing position with their arms at the side of their body. The inclinometer was placed on the arm just proximal to the elbow. The arm was actively elevated in a sagittal plane within the range of patient comfort. The measurement was recorded at the patient’s end-range of motion. The patient was returned back to the neutral position (zero degrees). The measurement was taken three times for both sides of the body.

External rotation: Active ROM was tested with the participant in the supine position. The inclinometer was placed on the distal forearm proximal to the wrist joint. The patient’s arm was supported on the bed in 45 degrees abduction, elbow 90 degrees flexion and the wrist joint in neutral. Once positioned, patients were asked to rotate their arm outwards within their available range without any discomfort and without lifting their arm from the bed. Once the end range was achieved, the measurement was recorded. The patient was returned to the neutral position. External rotation was recorded three times on each side.

Some of the times, a bed was not available due to the busy clinic. In those cases, the recliner in the clinic was used for the neck ROM and shoulder external rotation ROM provided that extra caution was taken to make sure that the patient position remained consistent for the measurements.

Muscle strength:

The Microfet 2 hand-held dynamometer is clinically accepted and reliable for measuring muscle strength when tested by a single person (Bohannon, 1986). The Microfet 2 is very easy to use and accepted to measure muscle strength accurately (Hamdi et al., 2008).

Flexion: The patient was in the sitting position at the edge of the bed. The shoulder, arm, and forearm were at the side of the body (or in a neutral position). The hand-held dynamometer was placed on the flexor surface of the arm, just proximal to the elbow.
joint. Force was applied to the dynamometer by the evaluator and the patient was asked to resist the force by raising the arm without flexing the elbow joint, within the comfort zone. The dynamometer was held for 6-8 seconds and the highest peak force was recorded. The patient relaxed briefly after each measurement was taken. The measurement was taken three times on each side. Patients did not report any pain during the use of the Microfet dynamometer on the arm.

External Rotation: The patient was seated in an upright position on a bed. The shoulder was in a neutral position with the elbow flexed at 90 degrees. The hand-held dynamometer was placed on the extensor surface of the forearm, just proximal to the wrist joint. Force was applied to the dynamometer by the evaluator and the patient was asked to resist the force by moving the forearm into external rotation with the elbow remaining by the side of the body (6-8 seconds) and the highest peak force was recorded. The patient was asked to relax before taking the second measurement. The measurement was taken three times on each side.

Both of the strength tests were isometric tests, in which the movements of the arm or forearm of the participants were not allowed. The participants were asked to resist the force produced by the evaluator without allowing any arm or forearm movement.

**Questionnaires**

The participants were provided with four patient-reported outcome measures. Participants were instructed to complete the questionnaires on site.

Patient Concerns Inventory-Level of Importance (PCI-LOI)

University of Washington-Quality of Life scale (UWQOL) (Ghazali, Cadwallader et al., 2013)
Shoulder Pain and Disability Index (SPADI) (Angst et al., 2011)

Neck Dissection Impairment Index (NDII) (Goldstein, Ringash, & Bissada, 2014)

The patients were scheduled for a routine surgical checkup at 1-month post-surgery. The ROM and strength measurements and questionnaires were assessed a second time during this checkup visit.

3.2 Outcome measures

Patient Concerns Inventory-Level of Importance (PCI-LOI)

The PCI is a simple patient-reported outcome that helps identify and articulate subjective concerns in routine outpatient settings. It allows patients to emphasize their specific concerns and seek attention about these from the health care provider. It is also capable of monitoring patients concerns and needs over the course of treatment; and it highlights the issues that patients are willing to discuss, guiding the health care team to provide necessary support (Ghazali et al., 2011; Ghazali, Kanatas et al., 2013; Ghazali, Roe, Lowe, & Rogers, 2013). Specifically this self-assessment tool helps to identify patients’ specific concerns (Rogers et al., 2009; Ghazali, Roe et al, 2013) related to HNC and its associated treatments. It includes 55 items that address issues ranging from general concerns to treatment-specific concerns. The PCI is reliable (Ghazali, 2012), simple and easy to use (Ghazali & Rogers, 2012) and its content validity has been determined for head and neck cancer patients (Ghazali et al., 2011; Ghazali, Lowe et al, 2012). It has been found to be reliable and accurately identify swallowing and speech dysfunction (Ghazali et al., 2012) and valid in HNC population (Rogers et al., 2009; Ghazali et al., 2011; Ghazali et al, 2012).
The PCI has four main domains with multiple issues incorporated in each domain:

Physical and Functional Well-being (30 issues);

Social Care and Social Well-being (9 issues);

Psychological, Emotional & Spiritual Well-being (14 issues);

Treatment-related concerns (2 issues).

The PCI also includes a domain for “Other concerns” that allows the patient to indicate any important issue that is not present in the checklist. Moreover, another section, “Top 3 concerns” allowed patients to identify their top concerns.

For this study, (with the permission of the developer) we added a 7-point rating scale for level of importance (LOI) to the PCI, hence our study tool was termed PCI-LOI. Each issue can be scored from 1 to 7, ranging from “none” to “very great” importance. The low score in PCI-LOI indicates low concerns. A score of “7” for an issue expresses that an individual is highly concerned about that issue. The scores are added under each domain to get a total domain score. Each of the four domain scores was added together to get the Total PCI-LOI score. Hence, a high score in Total PCI-LOI indicates high concerns and denotes a low quality of life. The validity and the reliability of the modified PCI-LOI needs to be assessed.

University of Washington-Quality of Life scale (UWQOL)

The UWQOL questionnaire for head and neck cancer patients has been used widely since the original version was introduced in 1993 by Hassan and Weymuller (Hassan & Weymuller, 1993; Laraway & Rogers, 2012). In the original description, Hassan and
Weymuller described the “advantages of the UWQOL, head and neck questionnaire are that 1) it is brief and self-administered, 2) it is multifactorial, allowing sufficient detail to identify subtle change, 3) it provides questions specific to head and neck cancer, and 4) it allows no input from the health provider, thus reflecting QOL as indicated by the patient” (Hassan & Weymuller, 1993; Rogers, Gwanne, & Lowe, 2002). The questionnaire underwent significant revisions since its first version. The inclusion of shoulder dysfunction, importance rating of the issues and a free text section for additional comments from patients has increased its use in HNC patients (Rogers et al., 2002). The UWQOL is reliable, reproducible (Weymuller, Alsarraf, Yueh, Deleyiannis, & Coltrera, 2001), well validated (Kazi et al., 2008), and fast and easy to administer for the patient. It provides clinically relevant information (Rogers et al., 2002) and the quality of life is indicated solely by the patient (Weymuller et al., 2001; Laraway & Rogers, 2012; Rogers & Lowe, 2010).

The current UWQOL-version 4 is a well-established questionnaire for patients with HNC (Kanatas & Rogers, 2008). The 12 domains have single questions related to pain, appearance, activity, recreation, swallowing, chewing, speech, shoulder, taste, saliva, mood and anxiety assessed over the last seven days. The response scale is from 0 (worst quality of life) to 100 (best quality of life) (maximum score for the Total UWQOL is 1200) (Rogers et al., 2002; Kazi et al., 2008; Rogers & Lowe, 2010; Lowe & Rogers, 2012; Metcalfe, Lowe, & Rogers, 2014). The UWQOL also inquired about the most important issues over the last seven days (“which issues have been the most important to you during the past 7 days”) where patients can report their top 3 issues from the domains. It also includes three global questions, one about how patients feel relative to the month before they developed cancer, one about general health-related QOL and another is QOL related to HNC. The possible responses are excellent, very good, good, fair, poor and very poor. They are scaled evenly from 0 to 100. In addition, there is a free text box in which patients can describe any other important issue.
The composite score is the arithmetic mean of the 12 individual domain scores (Rogers et al., 2002). Recent work by Rogers and colleagues (Rogers & Lowe, 2010; Rogers, Lowe, Yueh, & Weymuller, 2010) suggested two subscale scores; ‘Physical Function’ and ‘Social-Emotional Function’. The Physical Function subscale is the average of six single question scores - chewing, swallowing, speech, taste, saliva and appearance. The Social-Emotional Function subscale score is an average of the scores for anxiety, mood, pain, activity, recreation and shoulder function. These two subscales made the questionnaire more precise and increased its responsiveness. They are preferred to the single composite score. Hence, it is preferable to report both the Physical Function and Social-Emotional Function sub-score (Rogers et al., 2010; Rogers & Lowe, 2010; Lowe & Rogers, 2012).

The UWQOL has content, construct and face validity (Rogers, Scott, Chakrabati, & Lowe, 2008; Rogers & Lowe, 2009). The UWQOL version 4 is concise, simple and easy to complete. Evidence supports the responsiveness and the sensitivity of the UWQOL to changes over time and changes according to the patient’s feature (Rogers & Lowe, 2010). It has a minimal patient burden and in spite of being concise, it retains psychometric validity. Due to its conciseness and simplicity in scoring, it is suitable for busy clinics (Rogers et al., 2010).

Shoulder Pain and Disability Index

The Shoulder Pain and Disability Index (SPADI) is a self-administered questionnaire (Roach, Budiman-Mak, Songsiridej, & Lertratanakul, 1991) that was developed to measure the pain and disability of any shoulder pathology. The SPADI is highly responsive to change and can detect minimal change over time. It is well tested, short, detects treatment response and is easy to assess (Roach et al., 1991; Angst et al., 2011). The SPADI is very efficient in evaluating and identifying pain and disability in patients.
reporting shoulder pain (MacDermid, Solomon, & Prkachin, 2006). It is considered a valid, reliable tool especially in HNC patients who had neck dissection surgery (Roy, MacDermid, & Woodhouse, 2009; Marchese et al., 2012).

The SPADI has 13 items divided into two subscales (Roy et al., 2009; Goldstein et al., 2014). The “Pain” subscale consists of five questions related to severity of pain. The “Disability” subscale is evaluated by eight questions that measure the level of impediment of daily activities related to the shoulder. A 10 cm visual analogue scale is scored from 0 (denoting no pain/no difficulty) to 10 (denotes worst pain imaginable/so difficult required help). Given the two subscales, scores range from 0-50 and 0-80, with an overall score of 0-130, expressed as a percentage. The Total SPADI score is calculated by summation of each score and then the average Total SPADI is calculated. This average score is then converted to the Total SPADI percentage. A higher score in SPADI denotes greater disability and lower QOL.

**Neck Dissection Impairment Index**

The Neck Dissection Impairment Index (NDII) consists of 10 questions which evaluate the quality of life after neck dissection surgery (Taylor et al., 2002). The questions are related to daily activities that require shoulder and neck involvement. It asks the question about how much the patient has been bothered due to the cancer surgery. Each question has a 5-point response option: ‘not at all’, ‘a little bit’, ‘a moderate amount’, ‘quite a bit’ and ‘a lot’. A score of 1 indicates lower quality of life (bothered a lot) with more complaints and a score of 5 denotes fewer complaints and higher quality of life (not bothered at all). The total score is converted to a score out of 100. Lower scores indicate greater disability (Scott et al., 2007; Goldstein et al., 2014) and a lower QOL. The NDII is a valid and reliable tool to measure neck (Ackelman & Lindgren, 2002) and shoulder mobility in patients undergoing neck dissection surgery (Taylor et al., 2002).
3.3 Analytic Procedures

Sample size:

Within our recruitment timeline, a target of 30 participants was achievable for this study.

Estimation of the population distribution:

We estimated the population characteristics to assess whether the study sample would be representative of the HNC population. Because of the small sample size, our population was not normally distributed for most of the parameters. Hence we used non-parametric tests in this study.

Demographic information:

Demographic and medical data were obtained from patients and medical records respectively. The data included age, sex, dominant side, pain before surgery, type of surgery, type of reconstructive flap, pain reported pre- and post-surgery, and painful side post-surgery. Surgical notes were obtained from the patient’s medical record. Any other relevant history of shoulder, arm or neck impairments were also recorded from the patients.

Data analysis:

Raw data from the ongoing study were analyzed using SPSS software version 23 (IBM corp., USA). Initial descriptive statistics were calculated for demographic data to describe the sample at the baseline/pre-surgical time point.

Physical changes in strength and range of motion for shoulder and neck: We determined the median and interquartile (IQR) range for each of the shoulder and neck ROM measurements and the shoulder strength measurements, at both pre-surgical and 1-month
post-surgical time points. We used the average mean value of the ROM and strength measurements. To identify any significant changes in these functional motions and strength between the two time-points, we used the Wilcoxon signed rank test.

*Changes in patients’ concerns and overall QOL after neck dissection surgery*: To detect changes in patients’ concerns, we used four different questionnaires. We determined the median and IQR ranges for Total PCI-LOI, Total SPADI percentage, NDII standardized score and UWQOL composite score.

For PCI-LOI, the median and IQR values for the total score along with domain specific (Physical and Functional Well-being, Social Care and Social Well-being, Psychological, Emotional and Spiritual Well-being and the Treatment-related) scores were calculated.

For the UWQOL, the composite score was calculated by averaging the total UWQOL for each of the 12 questions. The “Physical Function” subscale is the average of the scores of- the “chewing, swallowing, speech, taste, saliva and appearance” items and the “Social-Emotional” subscale score is the average of the “anxiety, mood, pain, activity, recreation and shoulder function” items (Rogers et al., 2010). To determine if there was any significant difference in patient-reported outcomes between the two time points, we used a Wilcoxon signed rank test. We also determined the top three UWQOL concerns, where the patient could rate their top three concerns over the past seven days.

The total SPADI percentages were calculated using a specific formula given below.

Total SPADI score in points/130 x 100 = _____ SPADI percentage score; (Roach et al., 1991)

The NDII Standardized score was calculated as follows:

NDII standardized score = [(raw score - 10)/40] x 100; (Taylor et al., 2002)
Cross-sectional validity of the PCI-LOI questionnaire:

We assessed if there was any correlation between the PCI-LOI and the other three validated questionnaires at both the pre-surgery and 1-month post-surgery time points. To determine the association, we used Spearman’s Rank Correlation Coefficient. Specifically, we assessed if there was a significant relationship between the Total PCI-LOI and the UWQOL score, and the PCI-LOI domain scores and the UWQOL score. Moreover, we also determined if there was any relationship between the Total PCI-LOI, the Physical and Functional Well-being domain score and the SPADI and the NDII scores at both time points.
Chapter 4

4 Results

Participant Characteristics:

A total of 58 patients were approached for the study, among which 30 (20 males, 10 females) individuals agreed to participate. Due to the nature of the disease and stress related to the upcoming surgery, almost half of the patients approached chose not to participate in the study. After provision of informed consent, eight patients withdrew themselves from the study and one patient did not come back to the clinic for a follow-up visit.

The mean age of the participants was 66 years (min-max: 30-85 years). Prior to surgery, 17 (56.7%) patients reported pain with 11 (36.7%) patients reporting pain on the pre-surgical side. In total, 2 (6.7%) patients had radical neck dissection, 9 (30%) modified neck dissection, 18 (60%) selective neck dissection and 1 (3.3%) patient had extended neck dissection. Along with the neck dissection surgery, 15 (50%) patients also underwent a reconstructive procedure. The baseline descriptive, surgical details and reconstructive flap details are given in Tables 4.1 to 4.4.
Table 4.1 Baseline demographics of participants [n=30]

<table>
<thead>
<tr>
<th>Demographics</th>
<th>n (percent except for age)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
</tr>
<tr>
<td>Mean (minimum-maximum)</td>
<td>66 (30-85) years</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>20 (66.7)</td>
</tr>
<tr>
<td><strong>Dominant side</strong></td>
<td></td>
</tr>
<tr>
<td>Left</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Right</td>
<td>27 (90)</td>
</tr>
<tr>
<td><strong>Pain reported pre-surgery</strong></td>
<td></td>
</tr>
<tr>
<td>Pain present&lt;sup&gt;a&lt;/sup&gt;</td>
<td>17 (56.7)</td>
</tr>
<tr>
<td>No pain</td>
<td>13 (43.3)</td>
</tr>
<tr>
<td><strong>Painful side pre-surgery (n=16)</strong></td>
<td></td>
</tr>
<tr>
<td>Operated side</td>
<td>11 (36.7)</td>
</tr>
<tr>
<td>Non-operated side</td>
<td>3 (10)</td>
</tr>
<tr>
<td>Both sides</td>
<td>2 (6.7)</td>
</tr>
</tbody>
</table>

<sup>a</sup>1 patient reported pain in the mouth and jaw
Table 4.2 Post-surgical information of the participants

<table>
<thead>
<tr>
<th>Surgery</th>
<th>n (% )</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radical</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Modified radical</td>
<td>9 (30)</td>
</tr>
<tr>
<td>Selective</td>
<td>18 (60)</td>
</tr>
<tr>
<td>Extended</td>
<td>1 (3.3)</td>
</tr>
</tbody>
</table>

**Side of surgery**

<table>
<thead>
<tr>
<th>Side of surgery</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Left</td>
<td>16 (53.3)</td>
</tr>
<tr>
<td>Right</td>
<td>14 (46.7)</td>
</tr>
</tbody>
</table>

**Pain reported post-surgery**

<table>
<thead>
<tr>
<th>Pain reported post-surgery</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pain present</td>
<td>13 (61.9)</td>
</tr>
<tr>
<td>No pain</td>
<td>4 (19)</td>
</tr>
</tbody>
</table>

**Painful side post-surgery**

<table>
<thead>
<tr>
<th>Painful side post-surgery</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Operated side</td>
<td>12 (57.1)</td>
</tr>
<tr>
<td>Non-operated side</td>
<td>0</td>
</tr>
<tr>
<td>Both sides</td>
<td>1 (4.8)</td>
</tr>
</tbody>
</table>

a Total surgeries, n=30; b Participants followed up post-surgery, n=21, 17 patients reported on pain; c Missing data on post-surgical pain, no reason given=4
### Table 4.3 Reconstructive surgeries depending on flap area

<table>
<thead>
<tr>
<th>Reconstructive flap</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Free flap</strong></td>
<td></td>
</tr>
<tr>
<td>Radial forearm free flap</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Lateral arm flap</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Fibular flap</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Scapular flap</td>
<td>3 (10)</td>
</tr>
<tr>
<td><strong>Non-Free flap</strong></td>
<td></td>
</tr>
<tr>
<td>Pedicled flap</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Rotation flap</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td><strong>No flap</strong></td>
<td>15 (50)</td>
</tr>
</tbody>
</table>

Note: Two of the patients who had scapular flap underwent SND and one had RND. The patient having pectoralis major pedicled flap underwent extended neck dissection.

### Table 4.4 Reconstructive surgeries on the basis of impact on shoulder

<table>
<thead>
<tr>
<th>Reconstructive flap</th>
<th>n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Affecting shoulder</strong></td>
<td></td>
</tr>
<tr>
<td>Pectoralis major pedicled flap</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Scapular flap</td>
<td>3 (10)</td>
</tr>
<tr>
<td><strong>Not affecting shoulder</strong></td>
<td></td>
</tr>
<tr>
<td>Radial forearm free flap</td>
<td>6 (20)</td>
</tr>
<tr>
<td>Fibular flap</td>
<td>2 (6.7)</td>
</tr>
<tr>
<td>Lateral arm flap</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Infra-clavicular flap</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td>Cervical rotation flap</td>
<td>1 (3.3)</td>
</tr>
<tr>
<td><strong>No flap</strong></td>
<td>15 (50)</td>
</tr>
</tbody>
</table>
Participation during the study:

A total of 30 participants were enrolled in the study. At pre-surgery, some patients had physical morbidities not related to the malignancy. Some of the patients did not complete the measurement tests. The breakdown of participation is given in Figure 4.1 & 4.2.

58 were approached for consent

30 participants enrolled in pre-surgery and 21 continued up to 1-month

Measurements completed on operated side

Pre-surgery

Range of motion $^a$  
Flexion-29

Strength $^b$

Flexion -29

1-month

Range of motion $^a$

Flexion-18

Strength $^b$

External rotation-16

External rotation-15

Flexion-16

Flexion-18

Flexion-16

External rotation-15

External rotation-16

External rotation-15

External rotation-16

External rotation-15

Neck lateral rotation-29

Neck lateral rotation-14

Neck lateral rotation-14

$^a$ ROM= degree, $^b$ Strength= kg

**Figure 4.1: Participants completing measurements on operated side**
58 patients were approached for consent

30 participants enrolled in the study

8 withdrew themselves

1 did not come for F/U

21 participated at 1-month F/U

Questionnaires completed at Pre-surgery

PCI-LOI (30)

SPADI (30)

NDII (29)

UWQOL (29)

Questionnaires completed at 1-month

PCI-LOI (21)

SPADI (19)

NDII (19)

UWQOL (21)

Figure 4.2: Participants completing questionnaires (n)
At the 1-month time point, we had 21 patients who continued the study. The reason for withdrawal was mainly physical inability to perform the measurement tests and mental stress related to the disease and the treatment. Among the 21 patients who continued, some patients were unable to do the measurements because of the surgery. Many of them did not want to answer some part or any of the questionnaires at all. Hence, we had variation in the numbers of patients who participated. In our small sample, we had only 1 patient who received radiotherapy and 1 who received chemotherapy at 1-month as adjuvant therapy. No participant was referred for rehabilitation therapy during this time frame.

Data for statistical comparison:

We excluded missing data from the statistical analysis. Therefore, the sample size varied for each strength and ROM measure and each questionnaire. To compare any difference between two time points, we only considered those patients who had completed each of the ROM and strength measures, and the questionnaires at both time points. The data used for statistical comparison are provided in Table 4.5.
Table 4.5 Data for statistical comparison from each patient who completed measures at two time points

<table>
<thead>
<tr>
<th></th>
<th>n</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Range of Motion</strong></td>
<td></td>
</tr>
<tr>
<td>Flexion*</td>
<td>17</td>
</tr>
<tr>
<td>External Rotation*</td>
<td>15</td>
</tr>
<tr>
<td>Neck lateral rotation*</td>
<td>14</td>
</tr>
<tr>
<td><strong>Strength</strong></td>
<td></td>
</tr>
<tr>
<td>Flexion*</td>
<td>16</td>
</tr>
<tr>
<td>External rotation*</td>
<td>15</td>
</tr>
<tr>
<td><strong>Questionnaires</strong></td>
<td></td>
</tr>
<tr>
<td>PCI-LOI</td>
<td>21</td>
</tr>
<tr>
<td>SPADI</td>
<td>19</td>
</tr>
<tr>
<td>NDII</td>
<td>19</td>
</tr>
<tr>
<td>UWQOL</td>
<td>21</td>
</tr>
</tbody>
</table>

*operated side

PCI-LOI, Patients Concerns Inventory-Level of Importance; SPADI, Shoulder Pain and Disability Index; NDII, Neck Dissection Impairment Index; UWQOL, University of Washington Quality of Life
**Objective 1:** Detect physical changes in strength and range of motion for shoulder and neck on the operative side.

Once again, we had a variation in the numbers of participants at both time points. Participants in some cases failed to provide us with the measurements for both sides (operated or non-operated). Descriptive information on participants’ ROM and strength at pre-surgery and at 1-month post-surgery is given in Tables 4.6 and 4.7.
Table 4.6 Shoulder range of motion (ROM) before and at 1-month after surgery [n=number of patients, median ROM (degrees), IQR=interquartile range]

<table>
<thead>
<tr>
<th>ROM</th>
<th>Pre-surgery</th>
<th>1-month post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operated side</td>
<td>Non-operated side</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
</tr>
<tr>
<td>Flexion</td>
<td>29</td>
<td>148.00</td>
</tr>
<tr>
<td>External rotation</td>
<td>29</td>
<td>60.60</td>
</tr>
<tr>
<td>Neck lateral rotation</td>
<td>29</td>
<td>63.00</td>
</tr>
</tbody>
</table>
Table 4.7 Shoulder strength before and 1-month after surgery [n=number of patients, median strength (kg), IQR=interquartile range]

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pre-surgery</th>
<th>1-month post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operated side</td>
<td>Non-operated side</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------</td>
<td>------------------</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
</tr>
<tr>
<td>Flexion</td>
<td>29</td>
<td>5.95</td>
</tr>
<tr>
<td>External rotation</td>
<td>29</td>
<td>6.14</td>
</tr>
<tr>
<td></td>
<td>17</td>
<td>5.32</td>
</tr>
</tbody>
</table>


Tables 4.8 and 4.9 provide the data from those participants who completed all ROM and strength measurements at both time points; pre-surgery and 1-month post-surgery. Range of motion was significantly lower on the operated side at 1-month post-surgery for all measures (Table 4.8). Statistically lower strength values were found on the operated side at 1-month post-surgery for both strength tests. Moreover, in the non-operated side for external rotation, strength was significantly lower at 1-month post-surgery (Table 4.9).
Table 4.8 Comparison of shoulder range of motion (degrees) before and after surgery on completed data \( [n=number \ of \ patients, \ median \ ROM \ (degrees), \ IQR=interquartile \ range] \)

<table>
<thead>
<tr>
<th>ROM</th>
<th>Pre-surgery</th>
<th>1-month Post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operated side</td>
<td>Non-operated side</td>
</tr>
<tr>
<td>Flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>n \ Median \ IQR</td>
<td>n \ Median \ IQR</td>
</tr>
<tr>
<td>Flexion</td>
<td>17 146.30 20.80</td>
<td>17 154.30 22.80</td>
</tr>
<tr>
<td>External Rotation</td>
<td>15 66.00 35.30</td>
<td>18 64.00 38.70</td>
</tr>
<tr>
<td>Neck lateral rotation</td>
<td>14 68.70 20.60</td>
<td>14 66.80 25.60</td>
</tr>
</tbody>
</table>

*p<0.05, pre-surgery to 1-month post-surgery
Table 4.9 Comparison of shoulder strength (kg) before and after surgery on completed data [n=number of patients; IQR=interquartile range]

<table>
<thead>
<tr>
<th>Strength</th>
<th>Pre-surgery</th>
<th>1-month Post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Operated side</td>
<td>Non-operated side</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
</tr>
<tr>
<td>Flexion</td>
<td>16</td>
<td>5.77</td>
</tr>
<tr>
<td>External rotation</td>
<td>15</td>
<td>6.23</td>
</tr>
</tbody>
</table>

*p<0.05, pre-surgery to 1-month post-surgery;
We also analyzed if there was any difference between the operated side and the non-operated side of shoulder ROM and shoulder strength of the participants at each time point. To do the comparison with the operated side, the non-operative shoulder of each patient was used as an internal control. The difference between the operated and the non-operated side was compared within subjects for the analysis. There was no change in ROM and strength between both sides at pre-surgery, however, for the operative side, significantly lower ROM and strength were shown at 1-month post-surgery compared to the non-operative side. Table 4.10 and 4.11 show the comparison of shoulder ROM and strength respectively between the operated side and the non-operated side at both time points.

Table 4.10 Comparison of shoulder ROM between operated and non-operated side

<table>
<thead>
<tr>
<th>ROM</th>
<th>Operated side</th>
<th>Non-operated side</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
</tr>
<tr>
<td>Flexion (Pre-surgery)</td>
<td>16</td>
<td>145.50</td>
</tr>
<tr>
<td>ER (Pre-surgery)</td>
<td>15</td>
<td>66.00</td>
</tr>
<tr>
<td>Flexion (1-month)</td>
<td>16</td>
<td>116.70*</td>
</tr>
<tr>
<td>ER (1-month)</td>
<td>15</td>
<td>38.70*</td>
</tr>
</tbody>
</table>

*p<0.05, between operated side to non-operated side

n=number of patients; IQR=interquartile range, ROM= range of motion, ER= external rotation
Table 4.11 Comparison of shoulder strength between operated side and non-operated side (kg)

<table>
<thead>
<tr>
<th>Strength</th>
<th>Operated side</th>
<th></th>
<th></th>
<th>Non-operated side</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
<td>IQR</td>
<td>n</td>
<td>Median</td>
<td>IQR</td>
</tr>
<tr>
<td>Flexion (Pre-surgery)</td>
<td>15</td>
<td>6.09</td>
<td>2.90</td>
<td>15</td>
<td>5.68</td>
<td>3.13</td>
</tr>
<tr>
<td>External Rotation (Pre-surgery)</td>
<td>15</td>
<td>6.23</td>
<td>2.64</td>
<td>15</td>
<td>5.14</td>
<td>2.36</td>
</tr>
<tr>
<td>Flexion (1-month)</td>
<td>15</td>
<td>4.09*</td>
<td>2.32</td>
<td>15</td>
<td>5.59</td>
<td>2.14</td>
</tr>
<tr>
<td>External Rotation (1-month)</td>
<td>15</td>
<td>3.18*</td>
<td>1.73</td>
<td>15</td>
<td>4.73</td>
<td>2.00</td>
</tr>
</tbody>
</table>

*p<0.05, between operated side to non-operated side

n=number of patients; IQR=interquartile range
Objective 2. Evaluate changes in patients’ concerns and overall QOL after neck dissection surgery.

Descriptive statistics for patients completing the questionnaires at pre-surgery and 1-month post-surgery are described in Table 4.12.
<table>
<thead>
<tr>
<th>Patient-reported outcome</th>
<th>Pre-surgery</th>
<th>I-month Post-surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Median</td>
</tr>
<tr>
<td><strong>Total PCI-LOI</strong></td>
<td>30</td>
<td>93.5</td>
</tr>
<tr>
<td>Physical &amp; Functional Well-being&lt;sup&gt;a&lt;/sup&gt;</td>
<td>30</td>
<td>47.5</td>
</tr>
<tr>
<td>Social Care and Social Well-being&lt;sup&gt;b&lt;/sup&gt;</td>
<td>30</td>
<td>14.0</td>
</tr>
<tr>
<td>Psychological, Emotional &amp; Spiritual&lt;sup&gt;c&lt;/sup&gt;</td>
<td>30</td>
<td>21.0</td>
</tr>
<tr>
<td>Treatment related&lt;sup&gt;d&lt;/sup&gt;</td>
<td>30</td>
<td>4.5</td>
</tr>
<tr>
<td><strong>SPADI</strong></td>
<td>30</td>
<td>1.2</td>
</tr>
<tr>
<td><strong>NDII</strong></td>
<td>29</td>
<td>95.0</td>
</tr>
<tr>
<td>Composite UWQOL&lt;sup&gt;e&lt;/sup&gt;</td>
<td>29</td>
<td>85.4</td>
</tr>
<tr>
<td>Physical subscale</td>
<td>29</td>
<td>91.7</td>
</tr>
<tr>
<td>Social emotional subscale</td>
<td>29</td>
<td>79.2</td>
</tr>
</tbody>
</table>

<sup>a</sup> 30 items; min-max 30-210; <sup>b</sup> 9 items; min-max 9-63; <sup>c</sup> 14 items; min-max 14-98; <sup>d</sup> 2 items; min-max 2-14 (least to most important); <sup>e</sup> Min-max 0-100

n=sample size; IQR, interquartile range; PCI-LOI, Patient Concerns Inventory-Level of Importance; SPADI, Shoulder Pain and Disability Index; NDII, Neck Dissection Impairment Index; UWQOL, University of Washington Quality of Life
Once again, at pre-surgery, 30 patients completed the PCI-LOI, however only 29 patients completed the NDII, SPADI and UWQOL. At 1-month post-surgery, the participant number varied for each questionnaire. The statistics for patients who completed the questionnaires at both time points are given in Table 4.13. Non-parametric tests (Wilcoxon signed rank) determined that there was a significant difference between pre-surgical and 1-month post-surgical scores of SPADI, NDII and UWQOL scores. No statistically significant difference was found in the Total PCI-LOI score.

We also identified the ‘top 3’ concerns with 21 patients who completed the UWQOL at both time points (Table 4.14). “Pain” remained as an important concern until 1-month and “Shoulder” appeared as a new concern at 1-month.
Table 4.13 Comparison of patient-reported median outcomes before and after surgery for patients completing at both time points

| Patient-reported outcome | Pre-surgery | | | 1-month Post-surgery | | |
|-------------------------|-------------|-----------------|-----------------|-----------------|-----------------|
|                         | n | Median | IQR | n | Median | IQR |
| **Total PCI-LOI**       |   |         |     | 21 | 90.0   | 44.5 |
| Physical & Functional Well-being<sup>a</sup> | 21 | 46.0 | 28.0 | 21 | 58.0 | 28.5 |
| Social Care and Social Well-being<sup>b</sup> | 21 | 13.0 | 9.5 | 21 | 14.0 | 10.5 |
| Psychological, Emotional & Spiritual<sup>c</sup> | 21 | 21.0 | 23.0 | 21 | 23.0 | 9.5 |
| Treatment related<sup>d</sup> | 21 | 4.0 | 6.0 | 21 | 3.0 | 3.0 |
| **SPADI**               | 19 | 1.5 | 6.2 | 19 | 10.8* | 36.9 |
| **NDII**                | 19 | 95.0 | 27.5 | 19 | 55.0* | 42.5 |
| **Composite UWQOL<sup>e</sup>** | 21 | 88.8 | 14.4 | 21 | 77.5* | 18.1 |
| Physical subscale       | 21 | 95.0 | 11.3 | 21 | 86.7* | 22.1 |
| Social emotional subscale | 21 | 81.7 | 18.3 | 21 | 66.7* | 25.0 |

<sup>a</sup>30 items; min-max 30-210; <sup>b</sup>9 items; min-max 9-63; <sup>c</sup>14 items; min-max 14-98; <sup>d</sup>2 items; min-max 2-14 (least to most important); <sup>e</sup>Min-max 0-100

*p<0.05, pre-surgery to 1-month post-surgery, n=30; IQR, interquartile range; PCI-LOI, Patient Concerns Inventory-Level of Importance; SPADI, Shoulder Pain and Disability Index; NDII, Neck Dissection Impairment Index; UWQOL, University of Washington Quality of Life
Table 4.14 Top 3 concerns from the UWQOL (n=21)

<table>
<thead>
<tr>
<th>Rank</th>
<th>UWQOL ‘top 3’ Concerns</th>
<th>n</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pain</td>
<td>10</td>
<td>47.6</td>
</tr>
<tr>
<td>Pre-surgery</td>
<td>Anxiety</td>
<td>8</td>
<td>38.1</td>
</tr>
<tr>
<td>3</td>
<td>Mood</td>
<td>5</td>
<td>23.8</td>
</tr>
<tr>
<td>1</td>
<td>Pain</td>
<td>10</td>
<td>47.6</td>
</tr>
<tr>
<td>1-month</td>
<td>Shoulder</td>
<td>8</td>
<td>38.1</td>
</tr>
<tr>
<td>3</td>
<td>Activity</td>
<td>7</td>
<td>33.3</td>
</tr>
</tbody>
</table>
Objective 3: Assess cross-sectional validity of the PCI-LOI questionnaire.

We hypothesized that the PCI-LOI and UWQOL might correlate inversely. A high score in PCI-LOI will denote high concerns which would be associated with low QOL. On the contrary, a high score in UWQOL indicates better QOL which would be associated with lower concerns.

Correlations between the PCI-LOI and the UWQOL are provided in Table 4.15. Significant correlations were found for all comparisons except the Psychological Emotional & Spiritual Well-being domain of PCI-LOI at pre-surgery.

**Table 4.15 Correlations between PCI-LOI and UWQOL questionnaires on both time points:**

<table>
<thead>
<tr>
<th></th>
<th>PCI-LOI</th>
<th>UWQOL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-surgery</td>
<td>1-month</td>
</tr>
<tr>
<td></td>
<td>n=29</td>
<td>n=21</td>
</tr>
<tr>
<td>Total PCI-LOI</td>
<td>-0.625*</td>
<td>-0.695*</td>
</tr>
<tr>
<td>Physical &amp; Functional Well-being</td>
<td>-0.829*</td>
<td>-0.739*</td>
</tr>
<tr>
<td>Social Care and Social Well-being</td>
<td>-0.471*</td>
<td>-0.523*</td>
</tr>
<tr>
<td>Psychological, Emotional &amp; Spiritual</td>
<td>-0.269</td>
<td>-0.441*</td>
</tr>
</tbody>
</table>

* p < 0.05, PCI-LOI – Patient Concerns Inventory-Level of Importance; UWQOL – University of Washington Quality of Life Scale
The negative correlations denote that PCI-LOI scores and the UWQOL scores are inversely related. A higher PCI-LOI score means “greater concern” and hence lower QOL.

We also had a hypothesis that Total PCI-LOI score would correlate positively with SPADI and negatively with NDII.

Correlation between the PCI-LOI scores and the SPADI and the NDII scores are provided in Table 4.16. The Physical and Functional Well-being domain showed a significant positive correlation of 0.504 (p< 0.05) with the SPADI score at 1-month (Table 4.16). We did not find any significant correlation between PC-LOI and NDII scores.

<table>
<thead>
<tr>
<th>PCI-LOI</th>
<th>SPADI</th>
<th>NDII</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-surgery</td>
<td>1-month</td>
</tr>
<tr>
<td></td>
<td>n=30</td>
<td>n=19</td>
</tr>
<tr>
<td>Total PCI-LOI</td>
<td>0.107</td>
<td>0.417</td>
</tr>
<tr>
<td>Physical &amp; Functional Well-being</td>
<td>0.246</td>
<td>0.504*</td>
</tr>
</tbody>
</table>

* p < 0.05, PCI-LOI – Patient Concerns Inventory-Level of Importance; SPADI-Shoulder Pain and Disability Index; NDII- Neck Dissection Impairment Index
Chapter 5

5 Discussion

This study examined functional changes in the shoulder and neck along with changes in concerns of HNC patients undergoing neck dissection surgery. We identified changes in patients’ shoulder/neck mobility and shoulder strength after surgery. We also examined how their concerns changed over time following surgery. Our study also investigated if there were any significant changes in Total PCI-LOI scores before and after surgery, and if PCI-LOI scores correlated with other valid and reliable outcome measures used for HNC patients.

5.1 Shoulder/Neck ROM and Strength

In the HNC population, an alteration in physical function is not uncommon. One of the major issues in the post-operative HNC population is physical morbidity that restricts a persons’ ability to perform daily activities. One of the most significant post-surgical issues is shoulder morbidity (van Wilgen et al., 2003; Merve et al., 2009). Even after several modifications in the original neck dissection technique used to maintain the integrity of the SAN (Watkins et al., 2011), shoulder complaints have been reported in significant numbers (Leipzig et al., 1983; Dijkstra et al., 2001). In a cross-sectional study by Van Wilgen and colleagues, a significantly higher rate of dysfunction was reported in terms of neck pain, shoulder pain, reduced ROM, and loss of sensation (van Wilgen et al., 2004) post-surgery with radiotherapy. In our study, at 1-month post-surgery, we identified significant decreases in shoulder flexion, shoulder external rotation, and neck lateral rotation ROM on the operated side. We also observed significant reductions in strength for shoulder flexion and shoulder external rotation on the operated side. Except
for shoulder external rotation strength, no statistically significant differences were observed on the non-operated side. In our study, only one patient received radiotherapy at 1-month.

Hillel and colleagues (Hillel, Kroll, Dorman, & Medieros, 1989) reported that patients undergoing neck dissection surgery experienced some form of shoulder disability, pain and weakness. Although classical RND causes a higher percentage of shoulder disabilities, other forms of neck dissection (SND, MND) also significantly affect shoulder function (Leipzig et al., 1983; Sobol, Jensen, Sawyer, Costiloe, & Thong, 1985). A similar study (Laverick et al., 2004) was conducted to evaluate the HRQOL in HNC patients after neck dissection where an increase in shoulder dysfunction was found up to 6 months post-surgery. Shoulder strength was also reported to be decreased at 1-month post-surgery, but it returned to the baseline strength at 6 months follow up (Cheng, Hao, Lin, & Yeh, 2000). Neck dissection surgery significantly alters neck and shoulder function. In our study, with 60 percent SND, we detected significant decrease in strength. Other studies have also confirmed the adverse effect of neck dissection on neck and shoulder function (Chepeha et al., 2002; Cappiello et al., 2005; Scott et al., 2007; Carr, Bowyer, & Cox, 2009; Watkins et al., 2011; Schiefke et al., 2009).

Despite the fact that, with missing data on 9 people at 1-month, we did get significant results; there is a possibility that those missing data would have added more significance in our study. The most common reason for withdrawal was being unable to do the measurement tests due to either shoulder or neck pain. Another common reason was that participants were highly concerned about the outcome and effect of the total treatment procedure. Therefore, it is possible that the participants who were comparatively more unwell may have withdrawn from the study.
The shoulder ROM and strength (flexion and external rotation), from the operated side and the non-operated side in the same participant were shown to vary post-surgically in our study. We used the non-operated shoulder as a control for each participant. We detected significant lower ROM and strength at 1-month post-surgery in the shoulder (flexion, external rotation) between the operated side and the non-operated side in our within-subject analysis, however, no difference was found at pre-surgery. These results regarding shoulder strength are consistent with the results of Cheng et al (Cheng et al., 2000) who used a similar analytical strategy.

5.2 Patients concerns related to physical change and QOL

Patients with HNC are vulnerable to emotional and psychosocial problems along with a significant reduction in functional ability in daily life. Reduced social interaction and emotional expression in HNC survivors are greatly dependent on the functional and structural integrity of the head and neck region (Evans, Montgomery, & Gullane, 2009; Jones, Lund, Howard, Greenberg, & McCarthy, 2007). Along with the advancement in treatment, the control of non-metastatic tumors has improved and the number of HNC survivors has therefore increased. However, acute and late effects of the therapy have been reported from clinical observation. The late effects significantly impact QOL in the long term (Murphy, Gilbert, et al., 2007). Patient-reported outcomes or questionnaires are typically used to subjectively assess the HRQOL (Rogers, Forgie, et al., 2010).

We used four self-report questionnaires (PCI-LOI, SPADI, NDII, UWQOL) to identify patient concerns or changes in concerns over time. We added a “level of importance” measure to the original PCI. To date, no previous study has been reported to use the LOI scale. Our study shows no significant change in the Total PCI-LOI between pre-surgical and post-surgical time points. As noted before, the PCI-LOI has 55 items in total. The
patients score each of those 55 items according to the importance of each item to the patient. Some issues might be of great importance to patients before surgery, and some new issues may become important after treatment. The level of importance might vary widely before and after surgery, but it does not necessarily reflect on the total score, as some “very small” important issues might become of “very great importance” after the surgery. Conversely, “greatly” important issues might lose their importance after surgery. Therefore, a significant difference will not be evident in the total scores. To detect changes over time in particular issues, we will need to consider the domains separately, or at times we might need to specifically look for the particular issue we are interested in. The PCI-LOI includes all the probable concerns a patient might encounter during the course of treatment. Further studies are needed to understand and accurately use the PCI-LOI to detect changes in the level of importance of patients’ concerns.

Our study also reported statistically significant changes in SPADI, NDII, and UWQOL scores between the time points. UWQOL and NDII were specifically designed for HNC population. All three questionnaires are highly recommended for shoulder outcome measures (Eden, Flores, Galantino, & Spinelli, 2014).

The UWQOL and NDII also have been used specifically to quantify shoulder function and QOL in the HNC population (Hassan & Weymuller, 1993; Rogers, Scott, & Lowe, 2007; Murer, Huber, Haile, & Stoeckli, 2011; Swisher et al., 2012; Parikh, Tedman, Scott, Lowe, & Rogers, 2012). One study has shown the SPADI could detect impairment and disability of the shoulder in HNC patients following treatment (Swisher et al., 2012).

Studies show up to 80% of patients with HNC experience pain (Keefe, Manuel, Brantley, & Crisson, 1986; Foley & Inturrisi, 1987). Cancer pain is very significant and the prevalence in HNC cannot be underestimated (van den Beuken-van Everdingen et al.,
Several factors contribute to pain. The tumor itself causes pain due to compression along with direct invasion of bone, cancer infiltration of nerve roots, trunks or plexuses, local metastases, infection, ulceration, edema and inflammation (Carrol, Fine, Ruff, & Stepnick, 1994; Olsen, 1991; Talmi et al., 1997). Pain due to surgery or chemotherapy or radiation-induced mucositis is often reported (Epstein & Stewart, 1993; Pattison et al., 2015). Pre-treatment pain in HNC patients is found to be aggravated during treatment (Epstein & Stewart, 1993). The removal of the tumor along with musculoskeletal structures in the shoulder and neck muscles are also contributing factors for pain (Talmi et al., 2000). A prospective study showed 70% of patients had post-operative pain in the neck and shoulder during the first week post-surgery (Talmi et al., 2000). Short and colleagues also reported pain in the shoulder post-surgery (Short et al., 1984). Several other studies showed the prevalence of pain in HNC patients (Foley, 1987; Fialka & Vinzenz, 1988; Heico-Rüdiger, 1992). These studies support our study findings where “Pain” was identified as the top concern at both time points.

Psychological distress in HNC is common. Head and neck cancer patients experience psychiatric morbidity both in the head and neck outpatient clinic and during the course of their treatment (Siupsinskiene et al, 2008; Veer, Kia, & Papesch, 2010). Mood disorders like anxiety and depression cause significant morbidity to affect QOL in HNC patients (Murphy, Gilbert, et al., 2007). Several studies have demonstrated that patients experience considerable psychological issues during the course of treatment (Pandey et al., 2007; Buchmann, Conlee, Hunt, Agarwal, & White, 2013). A high score in “Anxiety” has been observed before the initiation of treatment in a study by Joseph and colleagues, in which the Hospital Anxiety and Depression scale was used. A gradual rise in

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6 Mucositis - Inflammation of the mucous membranes lining the digestive tract. Mucositis is a common side effect of chemotherapy and of radiotherapy that involves any part of the digestive tract.
depressive symptoms also have been observed in the same study from diagnosis to immediate post-treatment (Joseph et al., 2013). This agrees with our study where “Anxiety” was second (38.1%) among our ‘top 3’ concerns before treatment (UWQOL), and “Mood” was third (23.8%) most common. Due to the complex nature of the disease and the treatment, patients experience stressful factors. Fifty-eight percent of HNC patients have experienced some form of depression even before starting the treatment (A. M. Chen et al., 2009) and that continued to increase during treatment.

In our study, “Shoulder” was among the ‘top 3’ concerns at 1-month, ranked second and followed by “Activity”. According to our study, patients were not concerned about their mobility before the surgery. Their main issue was survival, represented by “Pain”, “Anxiety” and “Mood” being the ‘top 3’ concerns before treatment. At 1-month post-surgery, 8/21 (38.1%) reported “Shoulder” and 7/21 (33.3%) reported “Activity” to be among the ‘top 3’ concerns. This indicates that their concerns are changing over the course of treatment. Moreover, studies have shown that all of these top concerns at both time points predict a drop in QOL (Murphy, Ridner, et al., 2007). We have noticed that shoulder is an important concern at 1-month post-surgery that affects the HRQOL. The changes in QOL are picked up by both PCI-LOI and UWQOL. Hence, the overall decrease in shoulder-neck ROM and shoulder strength at 1-month post-surgery is reflective on the outcome measures. Long-term follow up would be needed to ensure whether the physical ability or concerns get better over time. It would be helpful to decide if an earlier rehabilitation program will be helpful for the patients. In a previous study, physiotherapy and exercise have been shown to reduce pain and shoulder morbidity over time and hence ensures better HRQOL in HNC patients (McNeely et al., 2008).

Our study provides an impression about the priorities of patients’ concerns at different time points over the course of treatment. “Shoulder” and “Activity” replaced “Anxiety”
and “Mood” from the baseline ‘top 3’ concerns. To improve QOL, these issues must be addressed and should be taken care of clinically. Future studies should consider following up patients over longer time periods and continue assessing physical and functional outcomes to gain better insight into shoulder and neck morbidity.

5.3 Cross-sectional convergent construct validity of Modified PCI-LOI

In our study, we also analyzed the validity of the PCI-LOI. Hence, we determined if there is any correlation between the PCI-LOI and other patient-reported outcome measures. The Total PCI-LOI score had a strong (Salkind, 2011) negative correlation (r = -0.625) with the total score of the UWQOL at pre-surgery. The Physical & Functional Well-being domain of PCI-LOI (r = -0.829) and the Social Care and Social Well-being domain (r = -0.471) also showed significant negative correlations with the total UQWOL. These results suggest that patients who are highly concerned before surgery according to the importance rating scale of the PCI, tend to have lower QOL. The HNC patients have several issues affecting them physically, psychologically and socially leading to lower QOL. During diagnosis and immediate post-surgical time points, morbidities affect the QOL (Hammerlid, Silander, Hö, & Sullivan, 2001). In our study, at pre-surgery the strong inverse relation between the Total PCI-LOI, the domain scores of PCI-LOI and the total UWQOL score, imply that as one’s level of importance for patients’ concerns increases, the perceived QOL deteriorates. A strong (Salkind, 2011) negative correlation between PCI-LOI and its domains with the UWQOL can be explained by higher patient concerns. At 1-month post-surgery, a strong (Salkind, 2011) negative correlation has been observed between the Total PCI-LOI and its physical domain with total UWQOL.
Moreover, the Psychological, Emotional and Spiritual domain had a statistically negative moderate correlation with UWQOL ($r = -0.441$) (Salkind, 2011).

Previous research has suggested a significant drop in QOL just after finishing the treatment (Hammerlid et al., 2001; Epstein, Robertson, Emerton, Phillips, & Stevenson-Moore, 2001) which is similar to our finding. A similar study has been done recently in our lab (paper yet to be published) which suggested a similar correlation between the PCI-LOI and the UWQOL. From both the studies, we agree that people reporting a higher level of importance for their concerns is associated with lower QOL.

We also observed moderate positive correlations between our Total PCI-LOI and Physical & Functional Well-being domain with the SPADI at 1-month ($r = 0.417$, $r = 0.504$, respectively). The correlation for the PCI-LOI domain was significant. There was no significant correlation found at pre-surgery between these variables. As previously discussed, the SPADI has two subscales relating to “pain” and “disability”. The SPADI inquires specifically about shoulder function and quality of life. On the contrary, PCI-LOI focuses on the “level of importance” of each issue listed in the tool that includes both physical issues and quality of life issues. There might be a presence of pre-existing shoulder conditions, not necessarily due to the malignancy, detected by the SPADI at pre-surgery. However, as they were unrelated to malignancy and hence might not be an important issue to patients at that particular time point, concerns on the PCI-LOI were not rated highly. At 1-month after the surgery, our patients were stressed by many issues and physical issues might be more concerning at that time. Shoulder pain and disability issues are easily identifiable at 1-month that is reflected on both the Physical & Functional Well-being domain of the PCI-LOI and the SPADI. Therefore, a moderate positive and statistically significant correlation was observed.
We also observed a moderate negative correlation between the Physical & Functional Well-being domain and the NDII. The NDII asks specifically about the treatment of the neck related to cancer. A higher score in the NDII reflects better neck morbidity. This also explains the negative correlation between the PCI-LOI subscale and the NDII. From our study, we can say that at 1-month post-surgery, the main concerns of the patients shifted from survival to other issues. Hence, the mobility issue becomes important and concerns related to the shoulder and neck mobility become prominent. The moderate correlation (Salkind, 2011) between the PCI-LOI domain and the NDII might be due to the fact, that patients start focusing on quality of life and other important physical and functional issues.

We did not observe any significant correlations between the total score of the PCI-LOI and SPADI, NDII at both time points. This may be due to the fact that the total PCI-LOI score is enriched with multiple related issues in the HNC population along with shoulder and neck morbidity. In contrast, the SPADI only focuses on shoulder morbidity and the NDII highlights neck morbidity. Hence, in the total PCI-LOI score, all four domains of the PCI-LOI are considered and so shoulder and neck issues are not necessarily highlighted as they are in the SPADI and the NDII. On the other hand, the Physical & Functional Well-being domain includes physical issues along with shoulder and neck morbidity and it might help to capture any changes in concerns related to shoulder or neck mobility. Our significant correlation of this subscale and the SPADI at 1-month explains that this subscale of the PCI-LOI might be able to help to detect shoulder and neck concerns.
5.4 Limitations:

The main aim of our study was to evaluate change in patients’ shoulder and neck ROM, shoulder strength and changes in patients concerns. Moreover, we also wanted to see if the PCI-LOI could detect changes in the level of importance in terms of shoulder and neck concerns after neck dissection surgery. As with any research work, some limitations should be considered.

First, our study had a small sample size and was not normally distributed. The ability to accurately estimate change in shoulder/neck functions or QOL may increase with a larger sample size.

Second, we followed patients to 1-month post-surgery and longer follow-up time points would have added more strength to this longitudinal study.

Third, we have found that it was difficult to get consent from the patient to participate in the study. Our HNC patients were already stressed about the disease and did not really want to get involved. Our participation rate of 51.7% demonstrates the scenario we faced in our study. Moreover, patients’ willingness to continue participating in the study was poor, leading to loss of follow-up data. The main reason for the loss of interest might be that the participants were overwhelmed with the whole procedure. The patients who withdrew had issues with their shoulder and neck mobility, which restricted them from doing the measurement tests. Despite this, we did show changes in strength and ROM measures of the shoulder as well as in the concerns of patients. However, we did have patients who chose not to continue the study because they were comparatively unwell and more stressed than the patients who decided to remain. There is a possibility that the patients who were feeling better wanted to continue in the study. This might lead to loss of information and is a source of bias in the study. There is a possibility that our analysis led to an underestimated result as the participants who were highly concerned about their
mobility and overall issues related to the surgery may have decided to discontinue the study.

Another issue that should be mentioned is that some patients lost their interest in the study after doing three ROM, two strength tests and four questionnaires; this led them to withdraw from the study or only participate in some of the future tests. Hence, our number of participants varied for each of the variables. Cancer itself is distressing enough for a patient to bear, so withdrawal from the study during follow-up was chosen by many of the patients. Larger sample sizes with longer follow-up will be helpful for future studies to detect a change in the level of importance.

We did not study whether there was any effect of reconstructive surgery in our sample separately. Another limitation is that, due to the busy nature of the clinic, an examination bed was not always available for shoulder measurement. So, in some cases, a recliner chair was used to measure the external rotation, which introduced a source of variation. This change in testing position at 1-month might have allowed greater range of motion for external rotation. This might bias our study. At 1-month the ROM might be less than we recorded while the measurement was performed on a recliner chair. So, the magnitude or direction of our study results might be biased and we might have under-estimated the decrease in ROM for external rotation.

We should also mention that the study topic might have biased the participants as they were already informed about the whole study. They might suspect that the study focus was shoulder and neck mobility, and there is a chance that they also focused too much on these issues or became more concerned about their neck or shoulder.
5.5 Directions for future research:

The study demonstrated a change in patient concerns and shoulder and neck morbidity (mobility and strength) in an individual affecting the QOL in HNC patients. First, as the change in shoulder and neck morbidity is established at 1-month post-surgery, it will be important to conduct similar research with longer follow-up times and a larger sample size. Since we have suggested that shoulder and neck mobility and shoulder strength is significantly reduced 1-month post-surgery, we need to follow-up the patient for longer durations to determine how that mobility changes.

Second, although the Total PCI-LOI score was correlated with the total UWQOL, it could not detect any significant changes between the time-points. Also, the correlation between PCI-LOI total score and NDII, SPADI score was not strong. Hence, the overall validity of PCI-LOI still needs to be researched. The ability to detect changes in concerns over time (i.e. responsiveness) is yet to be performed for HNC patients undergoing neck dissection.
Chapter 6

6 Conclusion

The study was designed to investigate and describe patients’ concerns and changes in patients’ concerns and shoulder/neck functionality. Patients’ concerns can be identified at different time points using patient-reported outcome measures. Our study showed a change in patients’ concerns before and after treatment. A change in shoulder/neck ROM and shoulder strength was also noticeable in our study. This indicates that individuals’ perceptions change over time according to their clinical condition. The PCI-LOI was significantly correlated with the UWQOL and the SPADI. We could not give conclusive results about the PCI-LOI being a valid tool, but we emphasize that the PCI-LOI has the potential as a useful tool for HNC patients. Combined use of the PCI-LOI and HRQOL measures routinely used with HNC patients would enable clinicians to get a better understanding of the patients’ needs.
References


works/?region=on


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Family Physician, 70(10), 1947–54.


Rogers, S. N., & Lowe, D. (2009). Screening for dysfunction to promote multidisciplinary intervention by using the University of Washington Quality of Life


Sturgis, E. M. (2014). International Head and Neck Cancer Epidemiology Consortium:


Appendix A – Ethics Approval Form
# Research Ethics

**Principal Investigator:** Dr. Ross Glassow  
**Title Number:** 0981-0  
**Review Level:** Exempt  
**Protocol Title:** Patient Concerns Following Head and Neck Surgery for Cancer  
**Department:** Institute of Oncology and Radiation Oncology  
**School:** Medicine and Dentistry  
**Western University:**  
**Research Fund:**  

**Ethics Approval Date:** May 14, 2014  
**Expiry Date:** September 30, 2016

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This is to certify that the University of Western Ontario Research Ethics Board (UWO REB) which acts under and according to the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and the Health Canada/Health Canada and Ethics Procedures, Conferences Guidelines, and Federal Legislation, and regulations of Ontario has reviewed and granted approval to the above referenced project(s) or amendment(s) for the approval extended above. The membership of the REB has approved the research or investigation requirement of REB as defined below in the Ethical and Drug Regulations.

The ethical approval for this study is to remain valid until the expiry date noted above assuming timely and appropriate responses to the REB's follow-up requests for same terms and amendments. If you require an amended approval prior to that, please submit a request using the University of Western Ontario Updated Approval Request Form.

A provision of the REB where deemed as investigators in research studies, or declare a conflict of interest, not participate in discussion related to, nor vote on, such studies when they are presented to the REB.

The Chair of the REB is Dr. Joseph Gilbert. The REB is regulated by the U.S. Department of Health & Human Services under the IRB regular registration N0100100400-00.

Ethics Officer to Contact for Further Information:

| Elke Beadle | Craig Kelly | Alina Meldred | Vikki Tom |

This is an official document. Please retain the original in your files.

Western University, Research Support Services 210, 1150  
London, ON, Canada N6A 3K7  
1-800-661-0235  
1-519-685-9356  
www.uwo.ca/research/services210
Appendix B – CRIC Approval Form
LAWSON FINAL APPROVAL NOTICE

LAWSON APPROVAL NUMBER:  R-14-167

PROJECT TITLE:  Patient Concerns following head and neck surgery for cancer

PRINCIPAL INVESTIGATOR:  Dr. Bert Chesworth

LAWSON APPROVAL DATE:  May 16, 2014

Health Sciences REB#:  105110

Please be advised that the above project was reviewed by the Clinical Research Impact Committee and Lawson Administration and the project:

Was Approved

Please provide your Lawson Approval Number (R#) to the appropriate contact(s) in supporting departments (eg. Lab Services, Diagnostic Imaging, etc.) to inform them that your study is starting. The Lawson Approval Number must be provided each time services are requested.

Dr. David Hill
V.P. Research
Lawson Health Research Institute

*All future correspondence concerning this study should include the Lawson Approval Number and should be directed to Sherry Paiva, Research Administration Officer, Lawson Approval, Lawson Health Research Institute, 750 Baseline Road, East, Suite 500.*

cc: Administration
Appendix C - Letter of Information
Letter of Information
Research Study: Longitudinal Evaluation of Patient Concerns After Surgery for Head and Neck Cancer

| Study Investigators: | | Study Investigators: |
|----------------------|-----------------------------|
| Bert Chesworth, PhD  | Tom Overend, PhD            |
| Associate Professor & Co-Supervisor |  Associate Professor & Co-Supervisor |
| School of Physical Therapy | School of Physical Therapy |

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<tr>
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<tr>
<td>Cathy Anderson, PT, MSc</td>
<td>John Yoo, MD</td>
</tr>
<tr>
<td>Physiotherapist</td>
<td>Chief - Dept. of Otolaryngology</td>
</tr>
<tr>
<td>London Health Sciences Centre, London</td>
<td>Victoria Hospital, London Health Sciences Centre</td>
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<tr>
<th>Kevin Fung, MD</th>
<th>Danielle MacNeil, MD</th>
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<tr>
<td>Associate Professor</td>
<td>Assistant Professor,</td>
</tr>
<tr>
<td>Dept. of Otolaryngology</td>
<td>Dept. of Otolaryngology</td>
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<tr>
<td>Victoria Hospital, London Health Sciences Centre</td>
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| Anthony Nichols, MD, Assistant Professor, Dept. of Otolaryngology | Tara Keating, PT, BScPT |
| Victoria Hospital, London Health Sciences Centre | Physiotherapist |
| London Health Sciences Centre | Victoria Hospital, London Health Sciences Centre |

<table>
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</thead>
<tbody>
<tr>
<td>Mariya Elsam, MSc (candidate)</td>
</tr>
<tr>
<td>Graduate Program in Health and Rehabilitation Sciences, Western University</td>
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Please initial to confirm reading this page __________

Page 1 of 5

Version 01-May-2014
Background Information and Purpose:
You are being invited to participate in a research study to determine the concerns of patients before and after the neck dissection surgery scheduled by your surgeon in the Otolaryngology Clinic at Victoria Hospital, London Health Sciences Centre. The purpose of this letter is to provide you with information that will allow you to make an informed decision about taking part in this study.

Details of the study:
We are asking you to participate because we wish to determine what your concerns are before and after the surgery. In addition we would like to know the effect of surgery on your shoulder and neck function by evaluating their mobility and strength, before and after surgery and during the course of your follow-up visits.

We are giving this letter of information only to people who are scheduled for neck dissection surgery at Victoria Hospital. If this situation does not apply to you, we would request you not to take part in this study.

This study is being conducted under the direct supervision of Dr. Bert Chesworth, who works at the School of Physical Therapy at Western University. He will supervise this study along with the following co-investigators: Dr. Tom Overend, Graduate supervisor, Associate Professor, School of Physical Therapy; Dr. John Yoo, Chief, Department of Otolaryngology, Victoria Hospital, London Health Sciences Centre; Dr. Kevin Fung, Associate Professor, Department of Otolaryngology, LHSC; Dr. Danielle McNeill, Assistant Professor, Department of Otolaryngology, LHSC; Dr. Anthony Nichols, LHSC, Assistant Professor, Department of Otolaryngology, LHSC; Cathy Anderson, Physiotherapist, LHSC; Tara Keating, Physiotherapist, LHSC; and Mariya Ehsan, graduate student, Health and Rehabilitation Sciences program, Faculty of Health Sciences, Western University.

If you agree to participate in this study you will be initially contacted by a nurse or surgeon in the head and neck clinic at Victoria Hospital, LHSC. The nurse or surgeon in the head and neck clinic will introduce you to Mariya Ehsan, our co-investigator, who will be collecting the information for this project. They will assist Mariya Ehsan with the consent process for patients willing to volunteer for the study.

Please initial to confirm reading this page

Version 01-May-2014
The data collection will start prior to your scheduled neck dissection surgery. Following the neck dissection surgery, data will be collected at 3 different time points:

- 3 to 4 weeks post-surgery prior to radiation treatment (data collected at the follow-up clinic visit)
- 3 months post-surgery after radiation treatment (data collected at the follow-up clinic visit)
- 6 months post-surgery (data collected at the follow-up clinic visit)

The study will include completion of the following questionnaires:
1. Patients Concerns Inventory (PCI)
2. Shoulder Pain And Disability Index (SPADI)
3. Neck Dissection Impairment Index (NDII)
4. University of Washington Quality of Life Scale

Mariya Ehsan will also be evaluating your shoulder and neck mobility and your shoulder strength using the following instruments:
1. Shoulder Mobility – a device to measure the amount of arm movement
2. Neck Movements – a device to measure the amount of neck movement
3. Shoulder Strength – a device that measures force generated by arm muscles

Health records of participants will be accessed to determine details of the surgery.

Risk and Benefits:
You will not be placed at any risk or harm in this study. You are expected to have some stiffness and pain in the shoulder and neck areas caused by the surgery, and there might be some discomfort while completing the questionnaires or while Mariya Ehsan measures the shoulder and neck movements and shoulder strength, but this is expected to be relatively mild and should abate quickly following the completion of the outcome measure tools.

There are no direct benefits to you due to your participation in the study but the results of the study can be helpful for future research and researchers. The results of the study will also help the clinical fraternity and patients in the future to have a better understanding about patients' concerns and surgical effects on their neck and shoulder function following surgery. Your participation in this project will not involve any additional costs to you, and you will not receive compensation for your participation.

Please initial to confirm reading this page __________

Version 01-May-2014
Confidentiality:
Your confidentiality will be respected. Your name and chart number are collected so that your hospital chart can be retrieved to obtain the details of your surgery. Your year of birth is obtained to calculate your age, since age is considered to be an important aspect of shoulder and neck mobility and function. This information will always be kept in a locked cabinet once Mariya Ehsan has completed collecting your data. No information that discloses your identity will be released or published, without your explicit consent to the disclosure. All records will be given a code number to be used on all data collection forms.

If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your explicit consent to the disclosure. All of the information collected will be kept in locked filing cabinets and shredded after seven years.

Representatives of Western University’s Health Sciences Research Ethics Board may contact you or require access to your study related records to monitor the conduct of the research.

Voluntary Nature of Study/Freedom to Withdraw or Participate:
Participation in this study is voluntary. You may refuse to participate, refuse to answer any questions or withdraw from the study with no effect on your future care at any time while in hospital or within one month following the conclusion of your involvement with the study. You do not waive any legal rights by signing the consent form.

If you agree to participate in this project, please sign the attached consent form, complete the contact information requested and return it to the person who gave this letter to you. You may keep this letter of information. A copy of your signed consent form will be made for you.

If you have any questions about this study, please contact Dr. Bert Chesworth at (********) or Mariya Ehsan at (*********)

Questions:
If you have any questions about your rights as a research participant or the conduct of the study you may contact Dr. David Hill, Scientific Director, Lawson Health Research Institute at (**********).

Please initial to confirm reading this page          Page 4 of 5

Version 01-May-2014
Primary Investigator
Bert M. Chesworth
BA, BScPT, MCIScPT, PhD
Associate Professor
Department of Physical Therapy
University of Western Ontario
London, Ontario

Please initial to confirm reading this page ___________ Page 5 of 5

Consent Form

Version 01-May-2014
Appendix D - Consent Form
Consent Form

"Longitudinal Evaluation of Patient Concerns After Surgery for
Head and Neck Cancer"

Principal Investigator:
Dr. Bert M. Chesworth, School of Physical Therapy, Western University

I have read the Letter of Information, have had the nature of the study explained to me
and I have agreed to participate. All questions have been answered to my satisfaction.

__________________________________________________________________________
Name of participant (Print)

__________________________________________________________________________
Signature of participant ___________________________ Date

__________________________________________________________________________
Name of person obtaining consent (Print)

__________________________________________________________________________
Signature of person obtaining consent ___________________________ Date

Version 01-May-2014
Appendix E: Patient Concerns Inventory- Level of Importance (PCI-LOI)
Appendix H - Head & Neck Cancer

Patient Concerns Inventory – Level of Importance Rating

We would like to know what is important to you with respect to undergoing Neck Dissection Surgery. Please indicate how important the following items are to you ‘during the last week’. For each item, please tick the box that indicates how important the issue is to you.

<table>
<thead>
<tr>
<th>PHYSICAL &amp; FUNCTIONAL WELL-BEING:</th>
<th>LEVEL OF IMPORTANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns</td>
<td>None</td>
</tr>
<tr>
<td>Appetite</td>
<td></td>
</tr>
<tr>
<td>Arm / hand</td>
<td></td>
</tr>
<tr>
<td>Bowel habits</td>
<td></td>
</tr>
<tr>
<td>Breathing</td>
<td></td>
</tr>
<tr>
<td>Chewing / eating</td>
<td></td>
</tr>
<tr>
<td>Coughing</td>
<td></td>
</tr>
<tr>
<td>Dental health / teeth</td>
<td></td>
</tr>
<tr>
<td>Dry mouth</td>
<td></td>
</tr>
<tr>
<td>Energy levels</td>
<td></td>
</tr>
<tr>
<td>Fatigue/tiredness</td>
<td></td>
</tr>
<tr>
<td>Hearing</td>
<td></td>
</tr>
<tr>
<td>Indigestion</td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td></td>
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<tr>
<td>Mouth opening</td>
<td></td>
</tr>
<tr>
<td>Mucus</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td></td>
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<tr>
<td>Pain in the head / headache</td>
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<tr>
<td>Pain in the neck</td>
<td></td>
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<tr>
<td>Pain elsewhere</td>
<td></td>
</tr>
<tr>
<td>Regurgitation</td>
<td></td>
</tr>
<tr>
<td>Salivation</td>
<td></td>
</tr>
<tr>
<td>Shoulder</td>
<td></td>
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<tr>
<td>Sleeping</td>
<td></td>
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<tr>
<td>Small</td>
<td></td>
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<tr>
<td>Sore mouth</td>
<td></td>
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<tr>
<td>Swallowing</td>
<td></td>
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<tr>
<td>Swelling</td>
<td></td>
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<tr>
<td>Taste</td>
<td></td>
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<tr>
<td>Vomiting / sickness</td>
<td></td>
</tr>
<tr>
<td>Weight</td>
<td></td>
</tr>
</tbody>
</table>
### SOCIAL CARE & SOCIAL WELL-BEING:

<table>
<thead>
<tr>
<th>Concerns</th>
<th>None 1</th>
<th>Very Small 2</th>
<th>Small 3</th>
<th>Moderate 4</th>
<th>Fairly Great 5</th>
<th>Great 6</th>
<th>Very Great 7</th>
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<tr>
<td>Home care</td>
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<tr>
<td>Lifestyle issues (smoking / alcohol)</td>
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<td>Recreational activities or hobbies</td>
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<td>Relationships</td>
<td></td>
<td></td>
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<tr>
<td>Speech / voice / being understood</td>
<td></td>
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<tr>
<td>Support for my family or friends helping with my care</td>
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<tr>
<td>Well-being of my dependents / children</td>
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<tr>
<td>Well-being of my spouse / partner</td>
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</tr>
</tbody>
</table>

### PSYCHOLOGICAL, EMOTIONAL & SPIRITUAL WELL-BEING:

<table>
<thead>
<tr>
<th>Concerns</th>
<th>None 1</th>
<th>Very Small 2</th>
<th>Small 3</th>
<th>Moderate 4</th>
<th>Fairly Great 5</th>
<th>Great 6</th>
<th>Very Great 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
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<tr>
<td>Anger</td>
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<tr>
<td>Anxiety</td>
<td></td>
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<tr>
<td>Coping</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Depression</td>
<td></td>
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<tr>
<td>Fear of the cancer coming back</td>
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<tr>
<td>Fear of medical or surgical complications</td>
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<td>Intimacy in relationships</td>
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<tr>
<td>Memory</td>
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<td>Mood</td>
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<tr>
<td>Self-esteem</td>
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<tr>
<td>Sexuality</td>
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<tr>
<td>Spiritual / religious aspects</td>
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<td>Personality &amp; temperament</td>
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<tr>
<td>TREATMENT RELATED:</td>
<td>LEVEL OF IMPORTANCE</td>
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<tr>
<td></td>
<td>None</td>
<td>Very Small</td>
<td>Small</td>
<td>Moderate</td>
<td>Fairly Great</td>
<td>Great</td>
<td>Very Great</td>
</tr>
<tr>
<td>Feeding tube</td>
<td></td>
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<tr>
<td>Wound healing</td>
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</tr>
</tbody>
</table>

**OTHER CONCERNS: (Please indicate below)**

Have we missed anything?

*Please indicate in your own words anything else that is important to you; but was not covered in the above sections*

<table>
<thead>
<tr>
<th>Other Concerns</th>
<th>LEVEL OF IMPORTANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>None</td>
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</tbody>
</table>

**TOP 3 CONCERNS: (Please indicate below)**

*In the space provided below, using your own words, please tell us your TOP 3 CONCERNS in the past week*

---

Thank you for taking the time to complete this questionnaire.
Your assistance in providing this information is very much appreciated.

Page 3

Adapted with the approval of the Evidence-based Practice Research Centre, Edge Hill University and the Aintree University Hospitals.
Appendix F: Shoulder Pain and Disability Index (SPADI)
## Appendix F

### SPADI (Shoulder)

Study Number: _______________  
Date: _______________

Time point: _______________

For the questions below, please circle the number that best represents your experience during the last week attributable to your shoulder problem.

### Pain Scale

How severe is your pain? (Circle the number that best describes your pain)

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Arthritis worst</td>
<td>No pain</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>2. When lying on involved side</td>
<td>No pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>3. Reaching for something on a high shelf</td>
<td>No pain</td>
<td></td>
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</tr>
<tr>
<td>4. Touching the back of your neck</td>
<td>No pain</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>5. Pushing with the involved arm</td>
<td>No pain</td>
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</tbody>
</table>

### Disability Scale

How much difficulty did you have? (Circle the number that best describes your experience)

<table>
<thead>
<tr>
<th>Question</th>
<th>Description</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Washing your hair</td>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. Washing your back</td>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. Putting on an undershirt or pullover sweater</td>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. Putting on a shirt that buttons down the front</td>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Putting on your pants</td>
<td>No difficulty</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6. Placing an object on a high shelf</td>
<td>No difficulty</td>
<td></td>
<td></td>
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<tr>
<td>7. Carrying a heavy object of 10 pounds</td>
<td>No difficulty</td>
<td></td>
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<td></td>
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<tr>
<td>8. Removing something from your back pocket</td>
<td>No difficulty</td>
<td></td>
<td></td>
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</tbody>
</table>

Version: 01-May-2014
Appendix G: Neck Dissection Impairment Index (NDII)
Appendix G

**Neck Dissection Impairment Index**

**Study Number** ___________  **Date** ___________

**Time point** ___________

As a result of the cancer **TREATMENT OF YOUR NECK**, how much have you been bothered by the following over the past 4 WEEKS? (Circle appropriate response)

1. Are you bothered by the neck or shoulder pain or discomfort? Not at all a little bit a moderate amount quite a bit a lot
2. Are you bothered by neck or shoulder stiffness? Not at all a little bit a moderate amount quite a bit a lot
3. Are you bothered by difficulty with self-care activities because of your neck or shoulder (for example, combing hair, dressing, bathing, etc)? Not at all a little bit a moderate amount quite a bit a lot
4. Have you been limited in your ability to lift light objects because of your shoulder or neck? Not at all a little bit a moderate amount quite a bit a lot
5. Have you been limited in your ability to lift heavy objects because of your shoulder or neck? Not at all a little bit a moderate amount quite a bit a lot
6. Have you been limited in your ability to reach above your head because of your shoulder or neck (for example, reaching from shelves, tables, or counters)? Not at all a little bit a moderate amount quite a bit a lot
7. Are you bothered by your overall activity level because of your shoulder or neck? Not at all a little bit a moderate amount quite a bit a lot
8. Has the treatment of your neck affected your participation in social activities? Not at all a little bit a moderate amount quite a bit a lot
9. Have you been limited in your ability to do leisure or recreational activities because of your neck or shoulder? Not at all a little bit a moderate amount quite a bit a lot
10. Have you been limited in your ability to do work (including work at home) because of your neck or shoulder? Not at all a little bit a moderate amount quite a bit a lot

Version: 01-May-2014
Appendix H: University of Washington- Quality of Life (UWQOL)
University of Washington Quality of Life Questionnaire (UWQOL)

This questionnaire asks about your health and quality of life over the past seven days. Please answer all of the questions by checking one box for each question.

1. **Pain.** (Check one box: = )
   - I have no pain.
   - There is mild pain not needing medication.
   - I have moderate pain - requires regular medication (codeine or nonnarcotic).
   - I have severe pain controlled only by narcotics.
   - I have severe pain, not controlled by medication.

2. **Appearance.** (Check one box: = )
   - There is no change in my appearance.
   - The change in my appearance is minor.
   - My appearance bothers me but I remain active.
   - I feel significantly disfigured and limit my activities due to my appearance.
   - I cannot be with people due to my appearance.

3. **Activity.** (Check one box: = )
   - I am as active as I have ever been.
   - There are times when I can't keep up my old pace, but not often.
   - I am often tired and have slowed down my activities although I still get out.
   - I don't go out because I don't have the strength.
   - I am usually in bed or chair and don't leave home.

4. **Recreation.** (Check one box: = )
   - There are no limitations to recreation at home or away from home. There are a few things I can't do but I still get out and enjoy life.
   - There are many times when I wish I could get out more, but I'm not up to it.
   - There are severe limitations to what I can do, mostly I stay at home and watch TV. I can't do anything enjoyable.

5. **Swallowing.** (Check one box: = )
   - I can swallow as well as ever.
   - I cannot swallow certain solid foods.
   - I can only swallow liquid food.
   - I cannot swallow because it "goes down the wrong way" and chokes me.

6. **Chewing.** (Check one box: = )
   - I can chew as well as ever.
   - I can eat soft solids but cannot chew some foods.
   - I cannot even chew soft solids.

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7. **Speech.** (Check one box: __ )

   - My speech is the same as always.
   - I have difficulty saying some words but I can be understood over the phone.
   - Only my family and friends can understand me.
   - I cannot be understood.

8. **Shoulder.** (Check one box: __ )

   - I have no problem with my shoulder.
   - My shoulder is stiff but it has not affected my activity or strength.
   - Pain or weakness in my shoulder has caused me to change my work.
   - I cannot work due to problems with my shoulder.

9. **Taste.** (Check one box: __ )

   - I can taste food normally.
   - I can taste most foods normally.
   - I can taste some foods.
   - I cannot taste any foods.

10. **Saliva.** (Check one box: __ )

    - My saliva is of normal consistency.
    - I have less saliva than normal, but it is enough.
    - I have too little saliva.
    - I have no saliva.

11. **Mood.** (Check one box: __ )

    - My mood is excellent and unaffected by my cancer.
    - My mood is generally good and only occasionally affected by my cancer.
    - I am neither in a good mood nor depressed about my cancer.
    - I am somewhat depressed about my cancer.
    - I am extremely depressed about my cancer.

12. **Anxiety.** (Check one box: __ )

    - I am not anxious about my cancer.
    - I am a little anxious about my cancer.
    - I am anxious about my cancer.
    - I am very anxious about my cancer.

---

Which issues have been the most important to you **during the past 7 days**?
Check up to 3 boxes.

<table>
<thead>
<tr>
<th>Pain</th>
<th>Swallowing</th>
<th>Taste</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Chewing</td>
<td>Saliva</td>
</tr>
<tr>
<td>Activity</td>
<td>Speech</td>
<td>Mood</td>
</tr>
<tr>
<td>Recreation</td>
<td>Shoulder</td>
<td>Anxiety</td>
</tr>
</tbody>
</table>
GENERAL QUESTIONS

Compared to the month before you developed cancer, how would you rate your health-related quality of life? (check one box: = )

- Much better
- Somewhat better
- About the same
- Somewhat worse
- Much worse

In general, would you say your health-related quality of life during the past 7 days has been:
(check one box: = )

- Outstanding
- Very good
- Good
- Fair
- Poor
- Very poor

Overall quality of life includes not only physical and mental health, but also many other factors, such as family, friends, spirituality, or personal leisure activities that are important to your enjoyment of life. Considering everything in your life that contributes to your personal well-being, rate your overall quality of life during the past 7 days. (check one box: = )

- Outstanding
- Very good
- Good
- Fair
- Poor
- Very poor

Please describe any other issues (medical or nonmedical) that are important to your quality of life and have not been adequately addressed by our questions (you may attach additional sheets if needed).
Appendix I: Surgical details form
Appendix E

Surgical Details Data Extraction Form

Longitudinal Evaluation of Patient Concerns After Surgery for Head and Neck Cancer

Study ID: __________________________ Extraction Date: ______________
Type of Surgery: __________________________
Date of Surgery: __________________________

Details of Surgery:

Version: 01-May-2014
Appendix J: Pre-surgical data collection form
Appendix C

Pre-surgical Data Collection Form
Longitudinal Evaluation of Patient Concerns After Surgery for Head and Neck Cancer

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Testing Date</th>
<th>Gender</th>
<th>Year of Birth</th>
</tr>
</thead>
</table>

Does the patient describe an affected/painful side?
Yes: No: If yes: Left: Right: Both:

<table>
<thead>
<tr>
<th>Dominant Side</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>M1</td>
<td>M2</td>
</tr>
<tr>
<td></td>
<td>M1</td>
<td>M2</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shoulder ROM</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Rotation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shoulder Strength</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>External Rotation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neck ROM</th>
<th>M1</th>
<th>M2</th>
<th>M3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extension</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotation (L)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rotation (R)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Version: 01-May-2014
Appendix K: Post-surgical data collection form
Appendix D  
Post-surgical Data Collection Form

Longitudinal Evaluation of Patient Concerns: After Surgery for Head and Neck Cancer

Study ID: ___________________________  
Testing Date: ________________________

Does the patient describe an affected/painful side? Yes: ________ No: ________  
Left: ___________  Right: ___________  Both: ___________

Measurement Occasion

3 to 4 weeks post surgery [ ] 3 months post surgery [ ]
6 months post surgery [ ]

Is the patient on chemotherapy? Yes: ________ No: ________
If yes: Start Date: ___________  End Date: ___________

Is the patient on radiotherapy? Yes: ________ No: ________
If yes: Start Date: ___________  End Date: ___________

<table>
<thead>
<tr>
<th>Shoulder ROM</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>M1</td>
<td>M2</td>
</tr>
<tr>
<td>External Rotation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Shoulder Strength</th>
<th>Left</th>
<th>Right</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion</td>
<td>M1</td>
<td>M2</td>
</tr>
<tr>
<td>External Rotation</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Neck ROM: M1 | M2 | M3
Rotation (L)  |     |     |
Rotation (R)  |     |     |

Version: 01-May-2014
Curriculum Vitae

Mariya Ehsan

Education:

January 2014 – to date
Master of Science,
Health and Rehabilitation Sciences
Western University
London, Ontario, Canada

March 2004 – July 2009
Bachelor of Medicine and Bachelor of Surgery,
Mymensingh Medical College, University of Dhaka
Dhaka, Bangladesh.

Honors and Awards:

2014-2016 Western Graduate Research Scholarship - Obtained award in the value of $12,000 per year for 2 years

2010 Recipient of “Best Intern in Ob/Gyn” award - Mymensingh Medical College & Hospital

2001-2003  Government Scholarship on Higher Secondary
          Based on Secondary School Certificate Examination

2001  Gold Medal Award: Received gold medal
       for academic excellence in Secondary Education
       1999-2000

1999-2000  Junior Scholarship (National Merit, Talent Pool)
            Mohammadpur Preparatory and Girl’s High School,
            Dhaka, Bangladesh.

Publication

1. Begum Mst. R., Akhter S., Ehsan M., Begum Mst. S., Khan F. Pretreatment and
   co-administration of oral anti-diabetic agent with clomiphene citrate or rFSH for
   ovulation induction in clomiphene-citrate-resistant polycystic ovary syndrome. 


   E. Beneficial Effects of Addition of Glucocorticoid during Induction of Ovulation


**CONFERENCE PRESENTATION**

1. Begum Mst. R., **Ehsan M.** Sclerotherapy with ethanol is effective and safe alternative to potentially complex surgical treatment of recurrent ovarian endometrioma.


**JOB EXPERIENCE**

January 2014 – Present  
Graduate Research Assistant,

Health and Rehabilitation Sciences

Western University

London, Ontario, Canada
January 2014 – January 2015  Graduate Teaching Assistant,

Health and Rehabilitation Sciences

Western University

London, Ontario, Canada

November 2012 – December 2013  Visiting Researcher,

Infertility Care and Research Centre Ltd.

Mohammadpur

Dhaka-1207, Bangladesh

January 2011 – October 2012  Medical Officer and Research Assistant,

Infertility Care and Research Centre Ltd.

Mohammadpur

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